

ΣfEE

HELLENIC ASSOCIATION OF PHARMACEUTICAL COMPANIES

THE PHARMACEUTICAL
MARKET IN GREECE

FACTS AND FIGURES

2014



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FOREWORD BY SFEE'S PRESIDENT

“The Pharmaceutical Market in Greece: Facts & Figures 2014”

It is with great pleasure to preface the renewed annual edition ‘**The Pharmaceutical Market in Greece: Facts & Figures 2014**’, conducted by SFEE’s Data Monitoring Committee in collaboration with the Health Economics Observatory of IOBE.

As it has been established during the past years from our association, this report intends to be **the most comprehensive overview of key facts and data of the pharmaceutical market in Greece** and the wider economic environment in which we are operating, trying to inform both our members and all other stakeholders in the broader health sector.

This year’s edition includes not only updates of main data contained in previous editions, but also new information relative to the health sector, while intending to objectively provide an explanation of key trends of last year (2014), compared to the current year.

More specifically this year’s edition covers trends regarding the evolution of public and private healthcare expenditure, the shaping of the overall pharmaceutical market, including OTC, the key factors that will affect future trends such as ageing population or dependency ratios and a brief summary of key macroeconomic data that affect the entrepreneurship of the pharmaceutical industry.

In an era dominated by Big Data, the need for decision-making and the shaping of a national health policy based on evidence should be the primary focus of all stakeholders, so as to demonstrate and exploit the added value of pharmaceuticals and not simply focus on the costing side while undertaking short term tax-based solutions.

We hope you find it useful

For the Data Monitoring Committee



Konstantinos Kofinas

General Secretary

For SFEE



Pascal Apostolides

President



THE PHARMACEUTICAL MARKET IN GREECE: FACTS & FIGURES 2014

This edition was composed and reviewed by the research staff of the Health Economics Observatory at IOBE with the active participation of SFEE's correspondent working group. The Data Monitoring Committee would like to thank Mr. Aggelos Tsakanikas, Assistant Professor at the National Technical University of Athens and Scientific Associate of IOBE, who along with the following IOBE researchers have undertaken the study for this year.

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1 EXECUTIVE SUMMARY

The **Greek economy** in 2014 showed positive growth of 0.8% for the first time after a six-year recession period (2007-2013) which had resulted in the fall of GDP by 26.3% or by €66 bln. At the same time, the major decline in revenues led to a significant decline in prices, thereby intensifying the recorded deflation, while the **unemployment rate** was reduced to 26.5% from 27.3% in 2013.

With respect to **demographic trends**, the negative trend in the natural change of the population highlighted by a difference between births and deaths of -21.592 persons for 2014 is expected to continue steadily for the next decades, resulting in an overall reduction of the Greek population until 2050, while significantly changing its age-group composition. In particular, it is expected that people **aged over 65 years** in Greece in 2050 will almost account for 1/2 of the total population (46.6%), thus deteriorating the **dependency ratio** and resulting in even greater pressures on the social security system.

Public pharmaceutical expenditure followed a downward trend for fifth consecutive year, as the target was reduced at €2 bln from €2.37 bln the previous year, thus, resulting in an overall decrease of 60.8% during the period 2009-2014. As expected, a similar trend has been observed re **public pharmaceutical expenditure per capita**, as it has been reduced from €456 in 2009 to €183 in 2014 ranking Greece in the bottom among EU countries. At this point, it should be noted that the aforementioned has been proven insufficient as proven by the **great contribution of the industry** through the mechanisms of rebates and clawback. Specifically, the pharmaceutical industry in 2014, **paid €226,4 mil in rebates and €201,8 mil in clawback to cover patient needs**, thus contributing with 21.6% of the actual pharmaceutical expenditure compared to 13.9% in 2013 and 9.4% in 2012.

Based on the latest available data, **health expenditure** in Greece reached €15.7 bil in 2013 (8.6% of GDP), out of which €10 bln (5.5% of GDP) accounted for **public health expenditure**. Expenditure for curative & rehabilitative care services amounting to €9.5 bln followed by pharmaceutical expenditure with €4.6 bln were the main expenditure components, in contrast to ancillary health care services (€833 mil) and health administration (€582.6 mil). **Hospital pharmaceutical expenditure** amounted to €1.6 bln demonstrating a decline of 9.4% compared to the previous year. The greater reduction in the individual categories comprising hospital expenditure was observed in expenditure for services (-18.2%) and the respective **pharmaceutical expenditure** (-13.7%).

Total sales of pharmaceutical products in terms of value to wholesalers/pharmacies amounted to €3.88 bln, indicating a fall by 2% compared to 2013, whereas sales to hospitals/EOPYY demonstrated an increase of 4.5% respectively. On the contrary, in **terms of volume** (number of packages sold) the latter presented a reduction of 3.6%, whereas sales to pharmacies/wholesalers showed an increase of 2.8%.

Penetration rate of patent protected medicinal products in 2014 reached 11.2%, percentage higher than in other European markets (EU average 7%), which can be, however, explained by the significantly lower prices in Greece (52% lower than EU average). Respectively, the share of non-protected medicinal products amounted to 64.2% (off patent 35% and generics 28.7%) higher than the previous years. According to latest available data, **over the counter** medicinal products (OTC) market size in 2014 amounted to €331 mil., showing an increasing trend compared to previous years, which is in line with the increased self-medication of patients prevailing this period.

Production of pharmaceutical products in Greece in value terms was estimated at €857 mil. in 2014, decreased by 2.8% compared to previous year. Overall, when compared to other national manufacturing sectors (24 in total), pharmaceutical industry is ranked 10th, showing a steady contribution in the domestic industrial production for the country.

Employment in the manufacturing of pharmaceutical products in Greece was estimated at 13.3 thousand people in 2014, showing an increase of 0.8% compared to 2013. In total, the workforce in the pharmaceutical industry represents 0.4% of total employment in the Greek economy and 3.6% of the respective labor force of the industrial sector, which is higher than the average of EE28 (2.1%).

Imports and exports of medicinal products amounted to €2.7 bln and €1.0 bln, respectively in 2014. Compared to last year, imports fell by 2.2% and exports by 0.7%, thus, lowering the pharmaceutical trade deficit at 3.1% or in absolute numbers - €1.6 bln compared to - €1.7 bln in 2013.

Table 1: The Greek pharmaceutical market in figures

Number of companies ⁽¹⁾	Manufacturers and Importers (2014)	~106
	Wholesalers (2014)	100
	Pharmacists Associations (2014)	27
Production ⁽²⁾	Domestic Production at ex-factory prices (2014)	€ 857 mil.
	% change 2013/2014	-2.8%
	Value added (2014)	€533 mil.
	Share of value added/Total of manufacturing (2013)	3.1%
Employment of pharmaceutical production ⁽³⁾	Number of employees (production) (2014)	13.3 thous.
	Number of employees (production) (2013)	13.2 thous.
	% change 2013/2014	0.8%
	Share of employment in production/total of manufacturing (2014)	3.6%
External trade ⁽⁴⁾	Exports Value (2014)	€1,049 mil.
	% change 2013/2014	-0.7%
	Imports Value (2014)	€2,698 mil.
	% change 2013/2014	-2.2%
Parallel Exports ⁽⁵⁾	Value terms (2014)	€306.7 mil.
Pharmaceutical Sales ⁽⁶⁾	To wholesalers / pharmacies (at retail prices)	€3,877 mil.
	To hospital (at hospital prices)	€1,399 mil.
	% change sales pharmacies/wholesalers 2013/2014	-2%
	% change sales hospitals 2013/2014	4.5%
Public Pharmaceutical Expenditure ⁽⁷⁾	Expenditure 2009	€5,108 mil.
	Expenditure 2014	€2,000 mil.
	Clawback 2014	€201.8 mil.
	Rebate 2014	€226.4 mil.
	Change public pharmaceutical expenditure 2009/2014	-60.8%
	Per capita public pharmaceutical expenditure (2014)	€183
	Public Pharmaceutical Expenditure / Sales of medicinal products (2014)	37.9%
Public Health Expenditure ⁽⁸⁾	Private pharmaceutical expenditure (2013)	€1,700 mil.
	Greece (value) (2013)	€10.021 mil.
	Greece (% of GDP) (2013)	5.5%
	European Union (% of GDP) (2013)	7.7%
Price Structure ⁽⁹⁾	Ratio of ex-factory price to retail price	67.4%
Demographic data ⁽¹⁰⁾	Life expectancy (2013)	81.4 years
	Dependency ratio (% population 0-14 years & 65+/ 15-64 years) (2014)	51.7%
	% of Uninsured	25.2%
Price Change ⁽¹¹⁾	Medicines Price Index 2009/2014	-26.5%
Generics ⁽¹²⁾	% of total sales (in value terms PPPs)	15.2%
	% of total sales (in volume terms)	28.6%
Generics and off-patent ⁽¹³⁾	% of total sales (in volume terms)	64.2%
OTC ⁽¹⁴⁾	Value (2014)	€331 mil.
Επενδύσεις R&D ⁽¹⁴⁾	Estimations (2014)	€100-120 mil.

(1) EL.STAT, EOPYY, Panhellenic Association of Pharmaceutical Wholesalers

(2) Eurostat 2015, PRODCOM

(3) Eurostat, Labour Force Survey, SBS, 2015

(4) Eurostat, International trade, EU Trade Since 1988 By CN8, 2015

(5) EOF, 2015

(6) System of Health Accounts (SHA) 2013, EOPYY 2012-2014, State Budget 2013-2014, data processing IOBE, SFEE, OECD Health Data 2015, Eurostat 2015

(7) SHA, 2013

(8) M.D 1907/B/15.7.2014, estimations IOBE & EFPIA 2014

(9) OECD Health Data 2015, Ministry of Labour, Atlas, 2014

(10) Eurostat, Harmonised Indices of Consumer Prices (HICP), 2015

(11) IMS 2014, Midas

(12) IMS 2014, Midas

(13) AESGP, IMS Hellas Data 2015

(14) EOF, 2014

3 ECONOMIC ENVIRONMENT

3.1 MACROECONOMIC INDICATORS

The Greek economy in 2014 exhibited positive growth of 0.8% after a six-year recession period (2007-2013), which had resulted in a fall of GDP by 26.3%, that is a loss of €66 bln of national income (from €251 bln to €187 bln), causing significant changes in the production of the economy with a significant number of businesses terminating their function. During the same period, unemployment recorded continuous escalation, reaching its highest levels historically at 27.5% in 2013. The major decline in revenues led to a significant decline in prices, thereby intensifying the recorded deflation until 2013.

The recovery in 2014 was fragile due to the exposure of the economy to high uncertainty, with the pre-election period heightening it and suspending the dynamic trend that had been created, primarily due to the strengthening of tourism.

Figure1: GDP (%change)

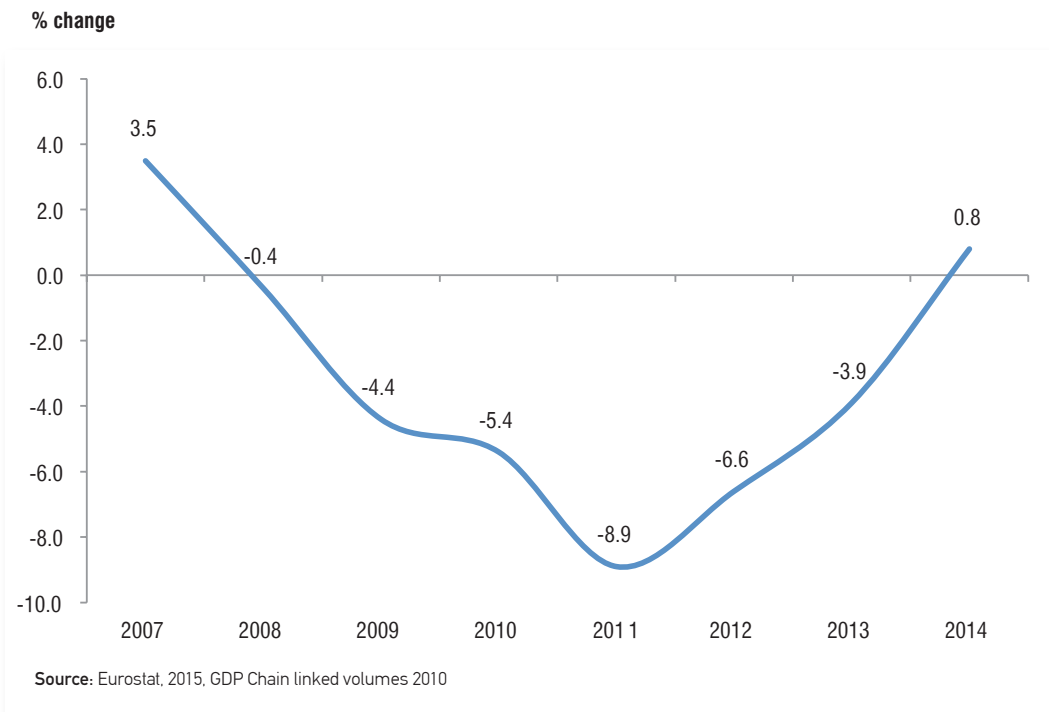
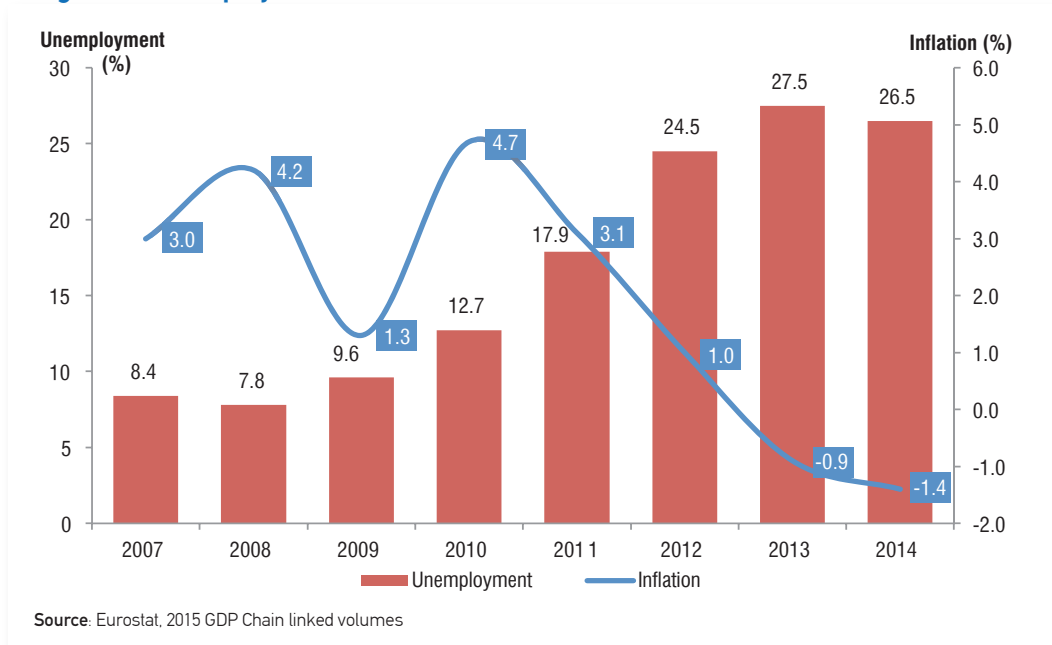
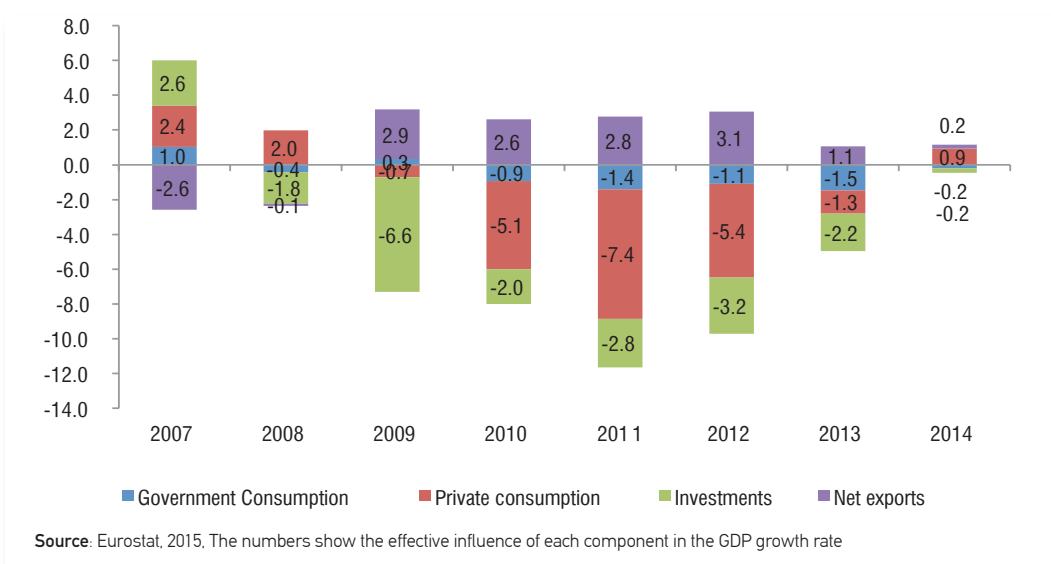


Figure 2: Unemployment and Inflation



The Greek recession period was signified not only by a reduction in GDP by ¼ but also by a restructuring in its components. In particular, until 2007 the Greek economy was mostly based on consumption (public and private), while investments were limited to cyclical fluctuations. Net Exports (exports-imports) usually worked negatively in GDP because of wide trade deficits. From 2008 onwards, the environment is reversed and public and private consumption fell significantly due to the decline in income, thus limiting the growth rate of GDP.

Figure 3: GDP determinants change



In particular, during the period 2010–2012, private consumption declined on average by ~5.9% which was counterbalanced by the restriction of imports and thus, the strengthening of net exports. From then on and especially in 2014, all GDP components were normalized and in combination with the correction of imbalances in the financial and commercial sectors, there was return to a positive rate of GDP growth (0.8%) and the turnaround of the primary fiscal deficit and current account deficit into surpluses. As a result, private consumption in 2014 was increased by 0.9% verifying the positive climate around the Greek economy.

4

DEMOGRAPHIC TRENDS AND HEALTH PROFILE OF THE NATIONAL POPULATION

4.1 DEMOGRAPHIC TRENDS

The number of births in Greece in 2014 amounted to 92,148 persons recording a 2.1% drop from previous year, while the number of deaths recorded an increase of 1.17% amounting to 113,740 persons respectively. As such, the natural population change (difference of births - deaths except migration) was negatively affected, resulting in an overall reduction of 21,592 people in the national population.

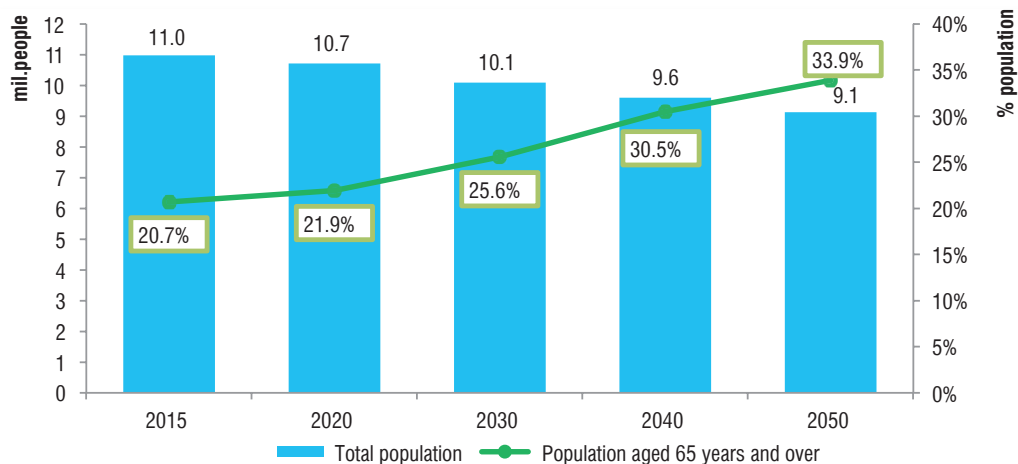
Table 2: Births-Deaths 1931 – 2014

Year	Births	Deaths	Natural change
1931	199,243	114,369	84,874
1950	151,134	53,755	97,379
1960	157,239	60,563	96,676
1970	144,928	74,009	70,919
1980	148,134	87,282	60,852
1990	102,229	94,152	8,077
2000	103,274	105,170	-1,896
2010	114,766	109,084	5,682
2011	106,428	111,099	-4,671
2012	100,371	116,668	-16,297
2013	94,134	111,794	-17,660
2014	92,148	113,740	-21,592

Source: EL. STAT, 2015

Based on the latest revision from Eurostat, this negative trend in the change of the population is expected to continue until 2050, thus, resulting in both an overall reduction of the population in Greece and a change in its composition, as reflected in Figure 4.

Figure 4: Projection of population, Greece, 2015-2050*

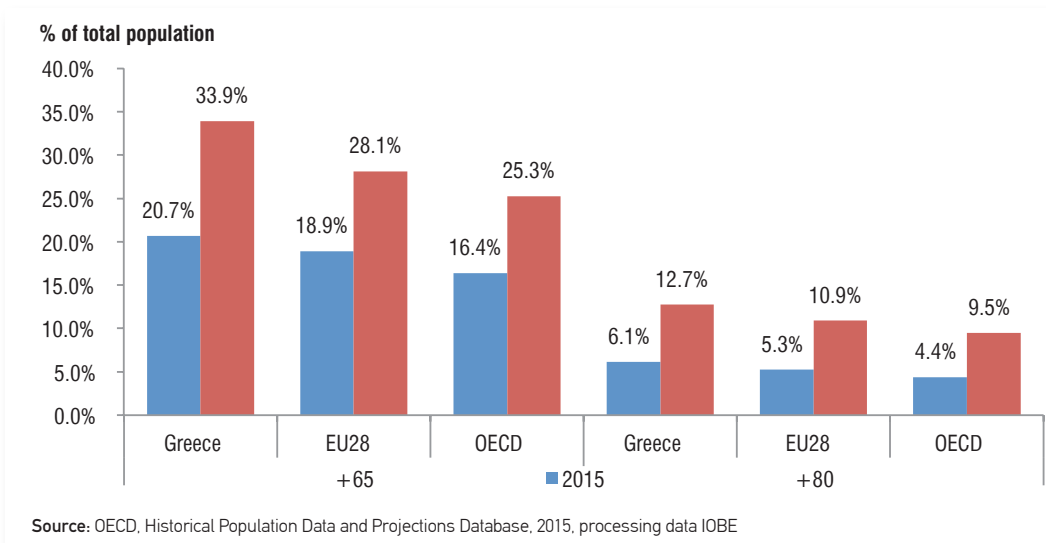


Source: Eurostat, Population Projections, 2014, data processing IOBE

*Not included the possible legalization of migration from 2015 onwards

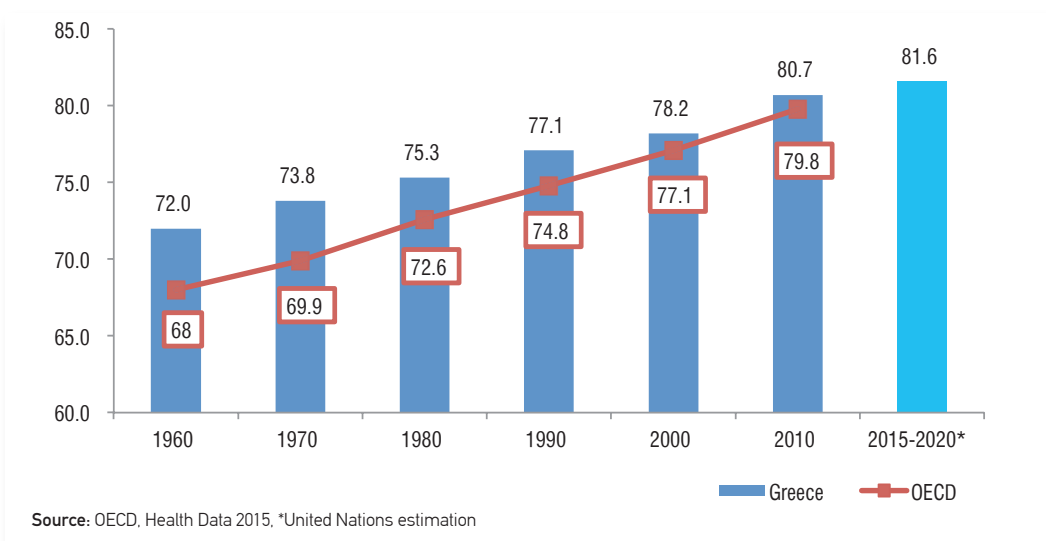
Explicitly, while in 2015 the percentage of people aged 65+ years in Greece is estimated at 20.7% of the total population, it is expected to cover 1/3 in 2050. Simultaneously, the proportion of over 80 years of age is estimated to double to 12.7%, in contrast to EU and OECD averages.

Figure 5: Projected shares of the population aged 65+ and 80+ 2015-2050, in Greece, EU-28 and OECD



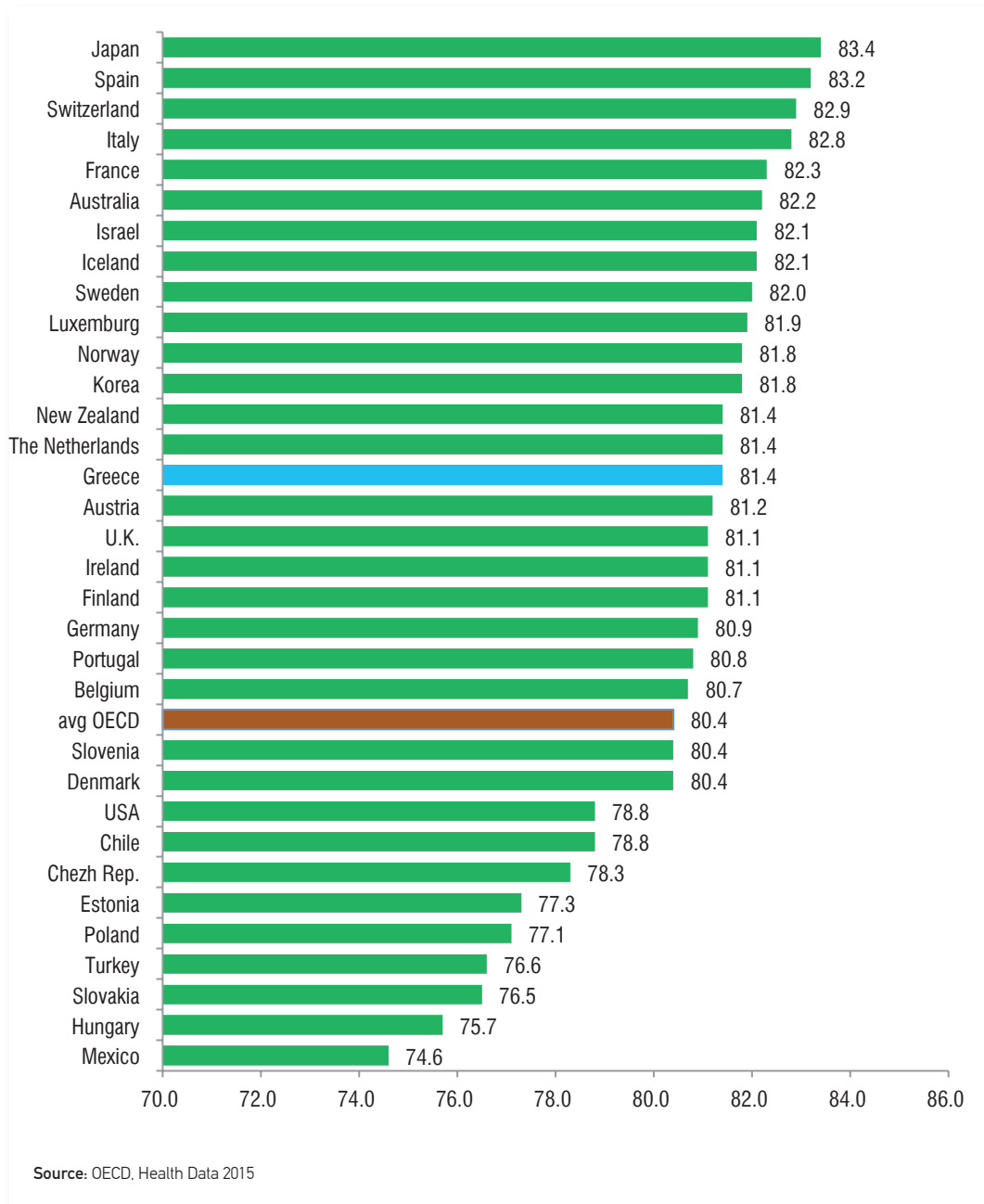
Life expectancy in Greece has increased considerably over the last 50 years, as it can be proven from the respective increase from 72 years in 1960 to 79.8 years in 2010 (Figure 6), due to technological advances, improvement in the provision of healthcare services, contribution of R&D and innovation of new drugs and therapies.

Figure 6: Evolution of life expectancy at birth in Greece, 1960-2010



According to OECD data, life expectancy in Greece reached 81.4 years in 2013, which is higher than the respective average of 80.4 years. The highest life expectancy was recorded in Japan, Spain, Switzerland and France (Figure 7).

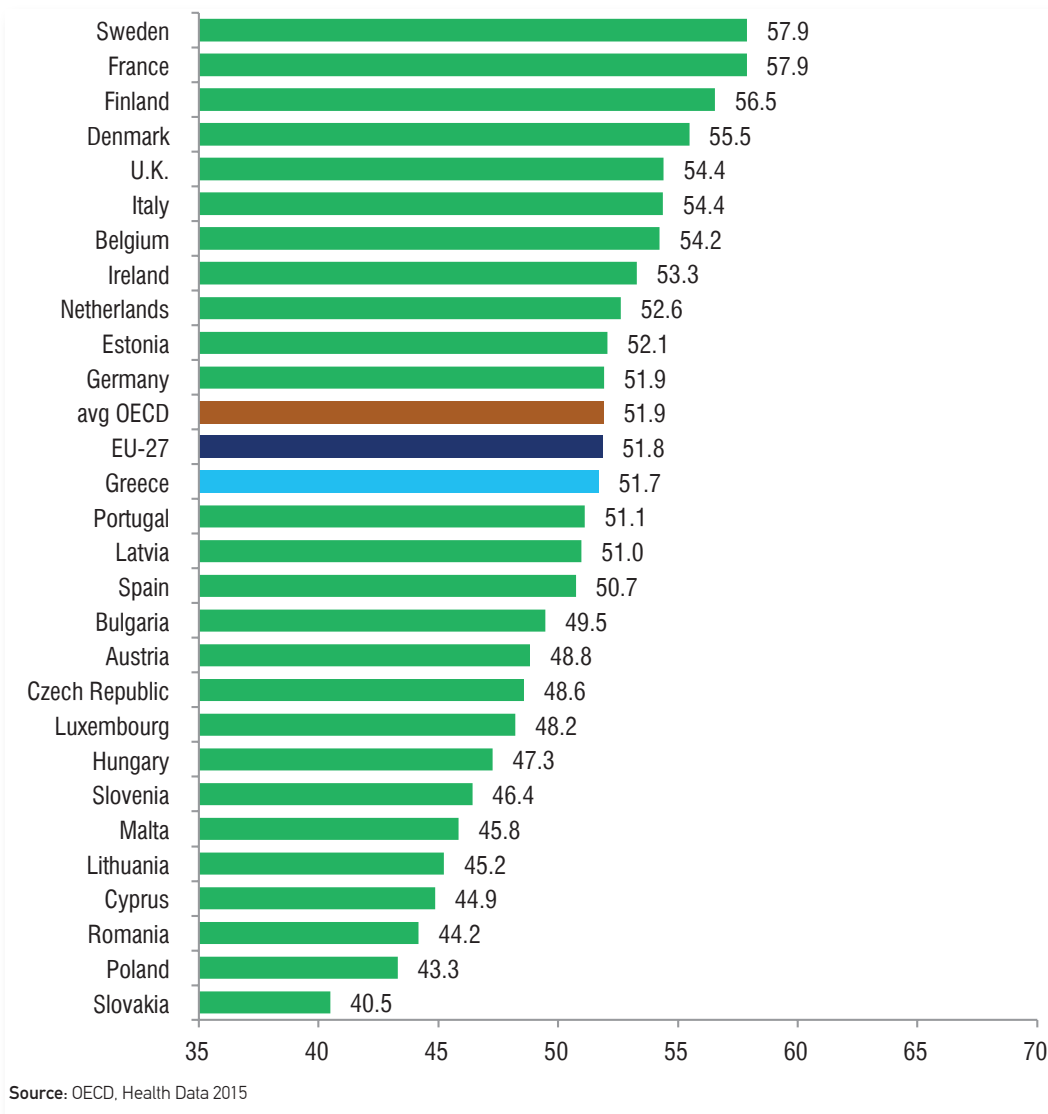
Figure 7: Life expectancy at birth in Greece and in the OECD countries, 2013



44.2 DEPENDENCY RATIO

The demographic changes directly affect population's dependency ratio. In Greece, nearly half of the population is dependent on the other half, and this proportion is expected to grow, signaling deterioration and increased pressure on social security systems, following the general tendency that currently exists in the developed countries¹. In particular, in 2014 Greece's dependency ratio reaches 51.7 and is close to the EU-27 average (51.8) and the average of OECD countries (51.9) (Figure 8).

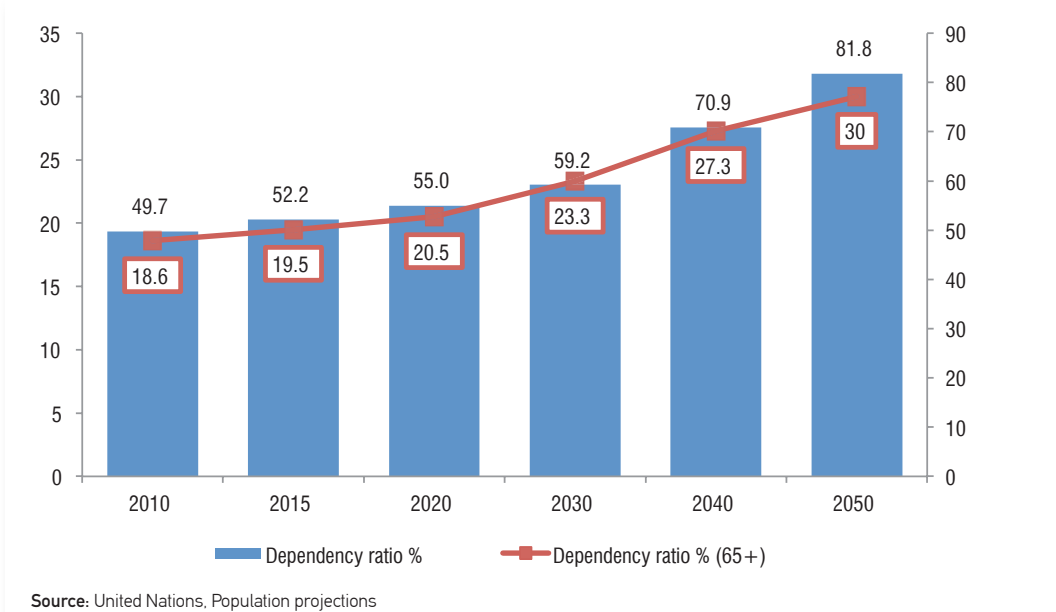
Figure 8: Dependency population ratio EU-27, 2014



1. Dependency population ratio shows the number of dependents (aged 0-14 and over the age of 65) to the total active population (aged 15-64). A high ratio means that the overall economy faces a greater burden in supporting the ageing population. This indicator is on an upward trend in advanced economies, reflecting rising life expectancy and declining birth rates.

According to United Nations estimations it is expected to amount 81.8% by 2050, as only in the age group 65+ the dependency ratio is expected to increase to 30% compared to 19.5% in 2015.

Figure 9: Dependency population ratio in Greece 2010-2050



Additionally, the uninsured consisted 25.2% of the total population in 2014. One can observe significant differences depending on the social security fund they belong to. The highest percentage of uninsured was found in IKA with 37.3% of the total uninsured population, followed by ETAA with 20.4%, whereas OGA and the Civil Servants' Sickness Insurance Fund (OPAD) had the lowest percentage, with 9.8% and 5.3% respectively.

Table 3: Insured and Uninsured 2014

Social Security Funds	Uninsured	Insured	Total	% Uninsured/Total
IKA	1,989.749	3,340.740	5,330.489	37.3%
OGA	161,326	1,484.014	1,645.340	9.8%
OAEF	160,537	855,159	1,015.696	15.8%
OPAD	68,882	1,238.558	1,307.440	5.3%
ETAA	36,479	142,187	178,666	20.4%
ESAA	29,150	120,125	149,275	19.5%
Oikos Nautou	28,823	132,521	161,344	17.9%
OTE.	19,220	108,267	127,487	15.1%
Rest	30,077	243,850	273,927	11.0%
Total	2,494.166	7,421.571	9,951.737	25.2%

Source: Ministry of Labour, Atlas, 2014

4.3 CAUSES OF DEATH

During the period 2009-2013, an increase in the number of deaths by 3.25% is recorded with cancer being the cause of death with the most significant increase (1,512 patients more, 5.5% vs. last year). According to Table 4 "other causes" recorded the greatest increase by 26.3% and in particular, deaths due to diseases of the digestive system and diseases of the genitourinary system which were the most frequent.

Table 4: Causes of Death 2009-2013

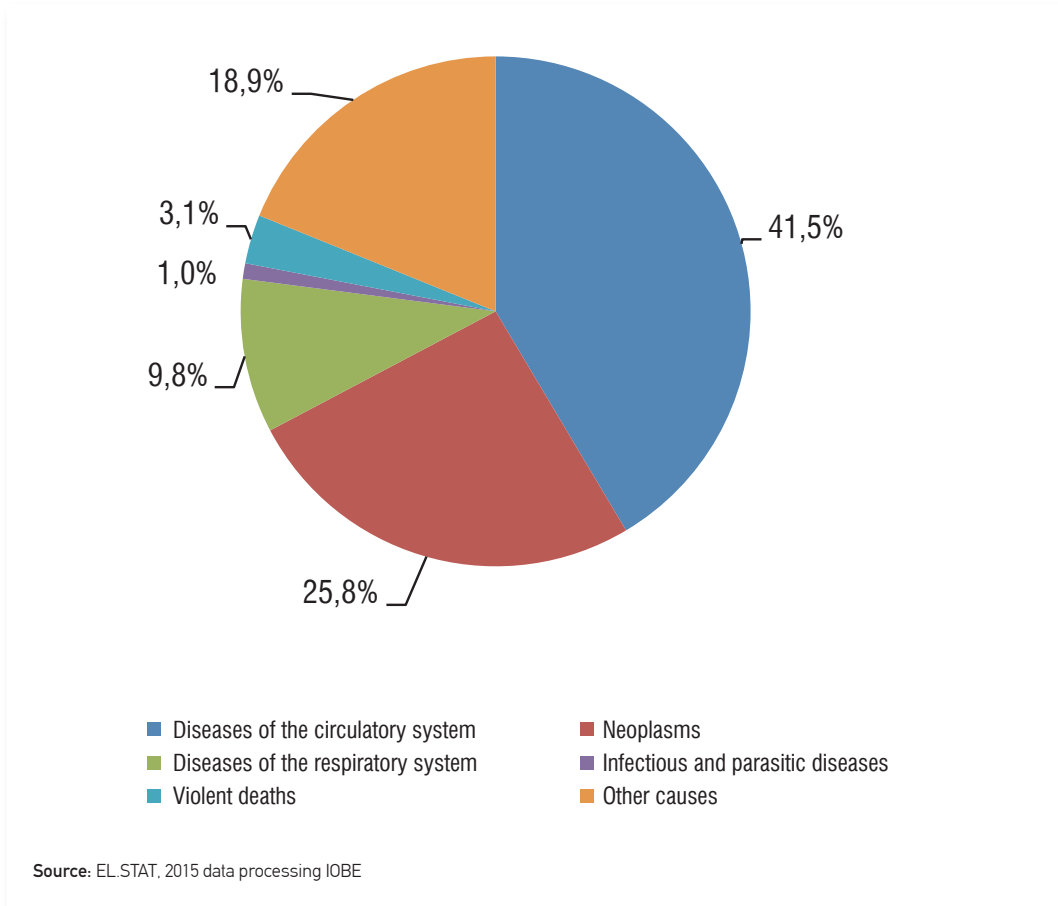
	2009	2013
1 Diseases of the circulatory system (of which)	48,453	46,342
<i>Heart disease</i>	31,976	30,212
<i>Cerebrovascular diseases</i>	15,493	14,996
<i>Other circulatory system diseases</i>	984	1,134
2 Neoplasms	27,345	28,857
3 Diseases of the respiratory system	10,770	10,924
4 Violent deaths (of which)	3,868	3,473
<i>Accidents related to transport</i>	1,647	1096
<i>Other accidents</i>	1663	1624
<i>Suicides</i>	391	533
<i>Homicides</i>	167	158
<i>Other violence *</i>	0	62
5 Infectious and parasitic diseases	1,183	1,105
6 Other Causes	16,697	21,093
Endocrine and metabolic diseases, nutritional deficiencies and immunity	1,404	1,759
Diseases of blood and blood-forming organs	211	481
Mental disorders	109	137
Diseases of the nervous system and sense organs	1,517	1,830
Diseases of the digestive system	2,585	3,049
Diseases of the genitourinary system	1,859	2,106
Complications of pregnancy, childbirth and the puerperium	4	0
Diseases of the skin and subcutaneous tissue	35	28
Diseases of the musculoskeletal system and connective tissue	426	371
Congenital anomalies	214	195
Certain conditions originating in the perinatal period	172	158
Symptoms, signs and indefinable conditions	8,161	10,979
TOTAL DEATHS	108,316	111,794

Source: EL.STAT., 2015, data processing IOBE

*Pursuant to the 9th Revision of the International Statistical Classification of Diseases, Injuries and Causes of Death (ICD-9) the following are included: cases when it is stated that an investigation by a medical or legal authority has not determined whether the injuries are accidental, suicidal or homicidal; deaths caused by injuries inflicted by law-enforcing agents (including military) on duty in the course of attempting to enforce the Law; deaths caused by injuries during war operations.

The basic cause of death were diseases of the circulatory system with 41.5% (heart diseases with 65%) followed by neoplasms with 25.8% and diseases of the respiratory system with 9.8%, as shown in Figure 10.

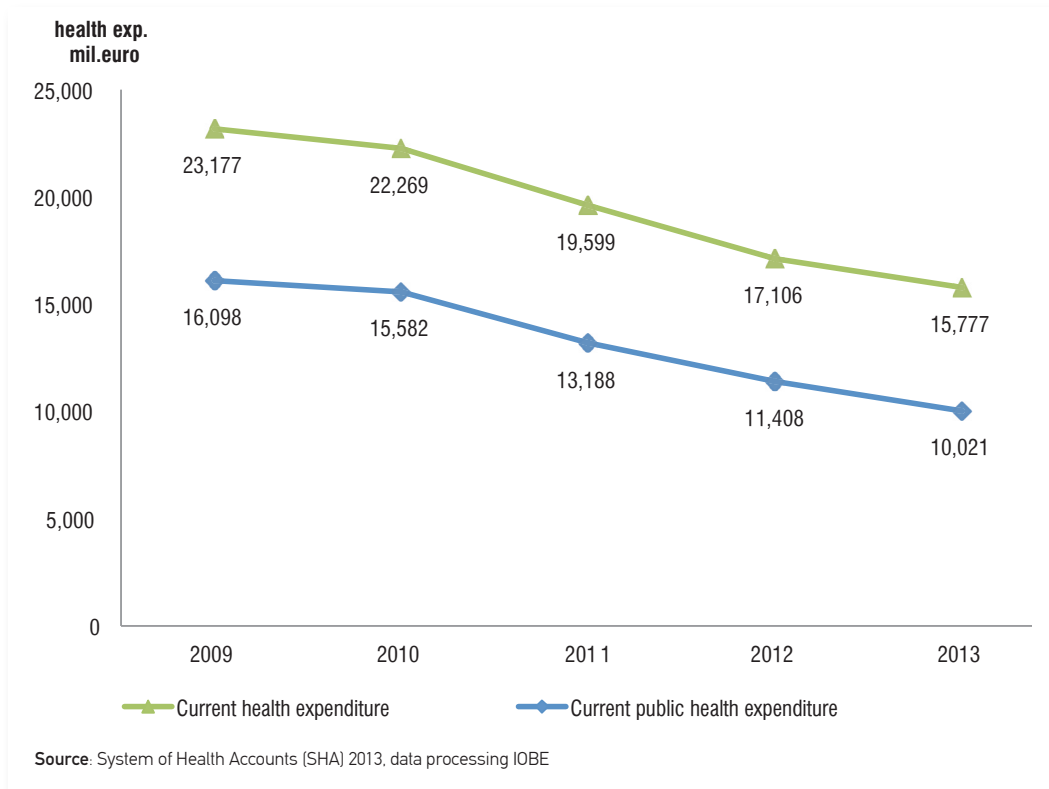
Figure 10: Causes of deaths in Greece, 2013



DEMAND SIDE: HEALTH AND PHARMACEUTICAL EXPENDITURE IN GREECE

In 2013 total health expenditure² in Greece amounted to €15.8 bln from which public expenditure amounted to €10 bln. During the period 2009-2013, the reduction in total health expenditure and subsequently in public health expenditure accounted for 31.9% and 37.8% respectively following the downward trend of GDP.

Figure 11: Health Expenditure & Public Health Expenditure (in mil. €)



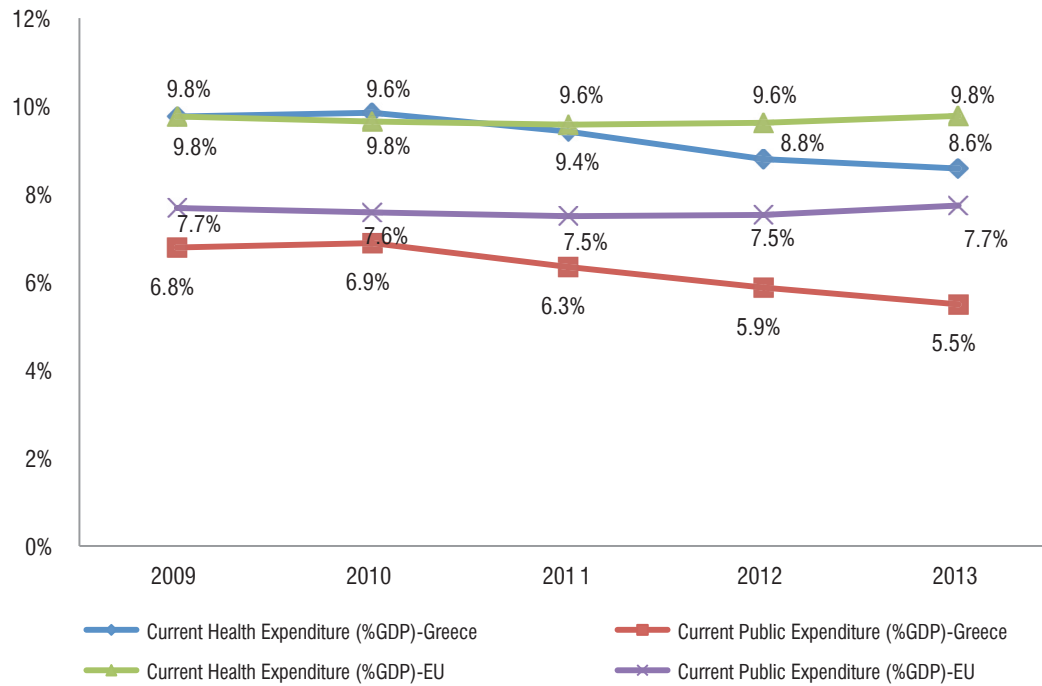
More precisely, total health expenditure as a percentage of GDP in 2009 accounted for 9.8%, whereas in 2013 for 8.6%³, proportion lower than both the EU average (9.8%) and the respective Eurozone average (available data for 17 countries, 10.2%). What is important to note is that the percentage of health expenditure in countries with similar economic problems is higher than in Greece and specifically, in Portugal and Italy it accounts for 9% and 8.8% respectively. Correspondingly, public health expenditure in Greece accounted for

2. The Hellenic Statistical Authority (ELSTAT) publishes statistical data for the Funding on Health Expenditures at national level based on the new System of Health Accounts manual SHA 2011 of the OECD, against SHA 1.0 that used for earlier data. The data have been revised based on the new methodology for the period 2009-2013.

3. It should be noted that according to OECD data the percentage of health expenditure is 9.2%, and has calculated with the old methodology SHA 1.0, while 8.6% correspond to the new SHA methodology 2011

5.5% of GDP in 2013 compared to 7.8% in the EU and 8.0% in the Eurozone, with Portugal and Italy standing at 6% and 6.8% respectively.

Figure 12: Health Expenditure & Public Health Expenditure as a % of GDP, Greece, Eurozone



Source: System of Health Accounts (SHA) 2013, EL-STAT, 2015, data processing IOBE

The pharmaceutical market is only a subset of the total health expenditure. However, due to the fact that the fiscal adjustment program has focused on the contraction of the pharmaceutical expenditure alone, its analysis is of significance. For a more complete understanding of the individual costs of pharmaceutical spending, it is necessary to clarify certain components, as presented below.

5.1 PHARMACEUTICAL EXPENDITURE

Data on “pharmaceutical expenditure” are often confused with data on “total pharmaceutical sales” released by the National Organization for Medicines (EOF).

EOF records sales of medicinal products from pharmaceutical companies to hospitals, wholesalers and pharmacies, on a monthly basis. On the other hand, according to the OECD’s International Classification of Health Accounts, with which Greek statistics have been harmonized, pharmaceutical spending is the total expenditure for medicinal products prescribed for outpatient care (non-hospital treatment). Therefore, **pharmaceutical expenditure is only a fraction of total pharmaceutical sales.**

More precisely, pharmaceutical sales are composed of:

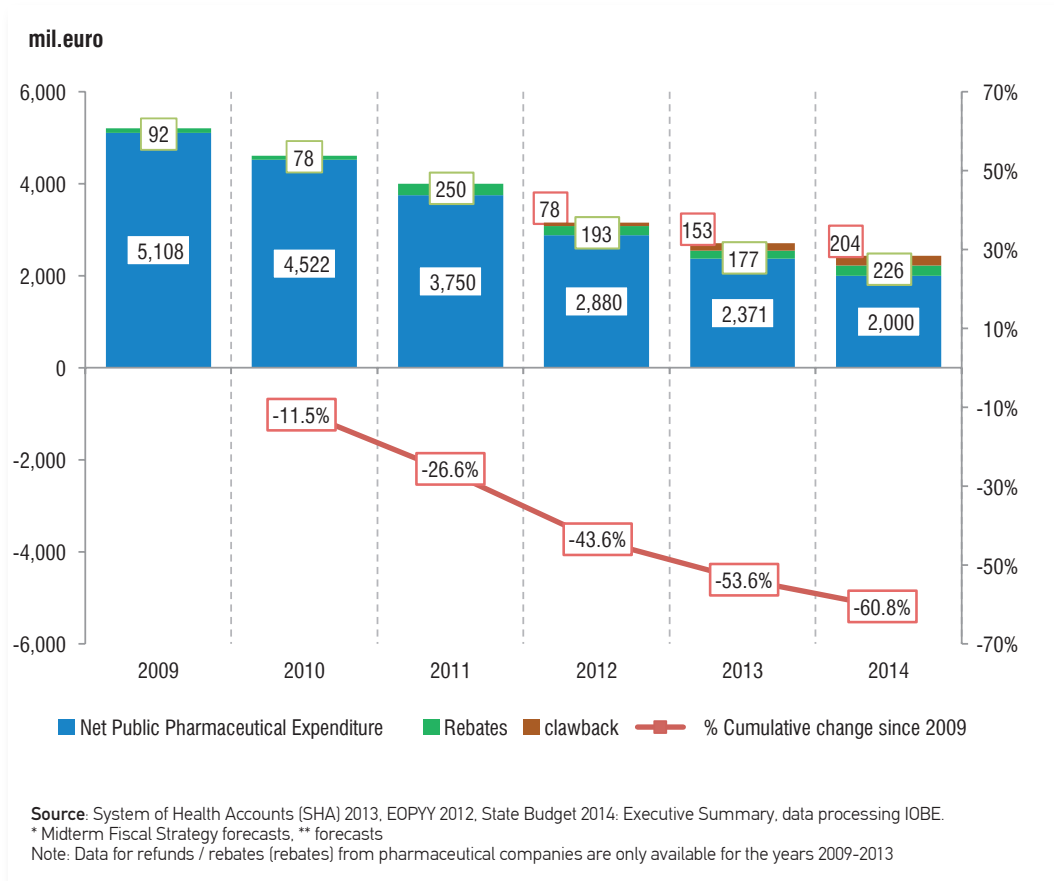
- (a) Public pharmaceutical expenditure which is incurred by social insurance funds (part is reimbursed to public funds, as it is inclusive of VAT 6.5% and mandatory discounts/ rebates/ clawbacks from pharmacists and pharmaceutical companies);
- (b) Hospital sales from pharmaceutical products (invoiced at hospital price = wholesaler price minus 8.74% - rebates);
- (c) Sales of pharmaceutical products that are re-exported (parallel exports);
- (d) Sales of pharmaceutical products to Greek citizens or tourists at their own cost;
- (e) Patient’s copayment, which does not put burden on social security funds.

Regarding point (b), it should be noted that pharmaceutical sales to hospitals are included in hospital expenditure, so they should be excluded from the analysis to avoid double-counting.

Regarding points (c) and (d), it should be noted that these sales are not part of public pharmaceutical expenditure; on the contrary, they generate revenue to the government, in the form of VAT, income tax, payroll tax, social security contributions, etc.

Public pharmaceutical expenditure is the final amount Social Security Funds have to spend to cover population needs, after deduction of rebates and clawback. In 2014, the respective target was set at €2 billion compared to €5.1 bln in 2009, resulting in an overall decrease of 60.8% the period 2009-2014.

Figure 13: Public Pharmaceutical Expenditure 2009-2014 (mil. €)



The reduction in public pharmaceutical expenditure from 2012 onwards has been proven greater than appropriate, leaving the state unable to meet patients' needs and thus, transposing a significant part of the economic burden to the private sector and specifically to the pharmaceutical industry. In particular, as shown in Table 5, the proportion with which pharmaceutical companies participate in the coverage of the actual public pharmaceutical expenditure, through clawback & rebates, is growing exponentially year by year, reaching 21.5% in 2014 from 9.4% in 2012.

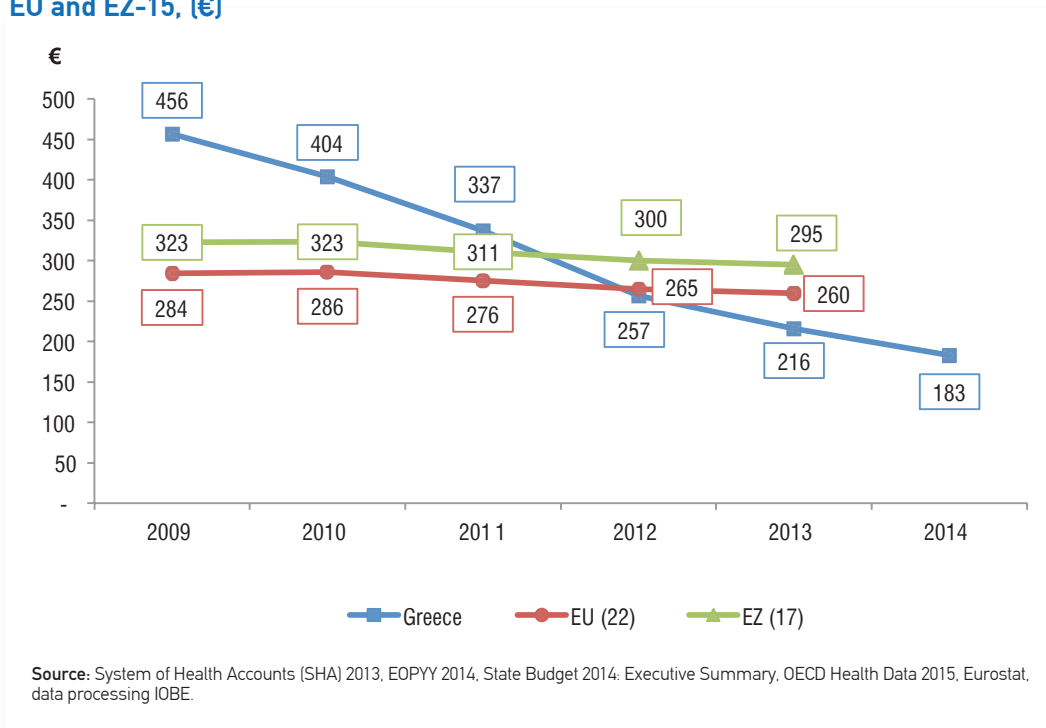
Table 5: Evolution of % contribution of the pharmaceutical industry in public pharmaceutical expenditure (target), 2012-2014

Year	Industry Rebates	Industry Clawback	Total (a)	Pharmaceutical expenditure (b)	% participation of industry in pharmaceutical expenditure
2012	€193 mil.	€78 mil.	€271 mil.	€2,880 mil.	9.4%
2013	€177 mil.	€153 mil.	€330 mil.	€2,371 mil.	13.9%
2014	€226 mil.	€ 204 mil.	€430 mil.	€2,000 mil.	21.5%

* Mandatory discounts such as simulation hospital price (8.74%), mandatory hospital discounts (5%) etc. are not included here.

As expected, similar downward trend was observed for **public pharmaceutical expenditure per capita**, where spending has been reduced from €456 per capita in 2009 to €183 in 2014 (Figure 14). This is compared with both the Eurozone (17 countries data available) and the EU averages (22 countries data available) evolution of the respective per capita expenditure that also follow a declining trend but at a smoother rate. Specifically, in 2013 the average public pharmaceutical spending per capita the EU average was reduced to €260 from € 284 originally in 2009 and respectively the Eurozone average to €295 in 2013 from €323 in 2009.

Figure 14: Per capita Public Pharmaceutical expenditure in Greece, EU and EZ-15, (€)



5.2 HEALTH EXPENDITURE & PHARMACEUTICAL EXPENDITURE

Health expenditure, according to the new SHA methodology 2011 is comprised of the respective expenditure for:

Care Services, Rehabilitation

- HC.1 Hospitals (public and private)
- HC.2 Residential. Long-term care facilities
- HC.3 Providers of ambulatory health care

Ancillary Health Care Services

- HC.4 Providers of ancillary services (eg. clinical diagnostic imaging and laboratory services, patient transport and emergency rescue services)

Products Supply for Outpatient Patients

- HC.5 Retailers and other providers of medical goods (pharmaceuticals, vision glasses, hearing aids, orthopedic belts and accessories)

Other Medical Products, Healthcare Management etc

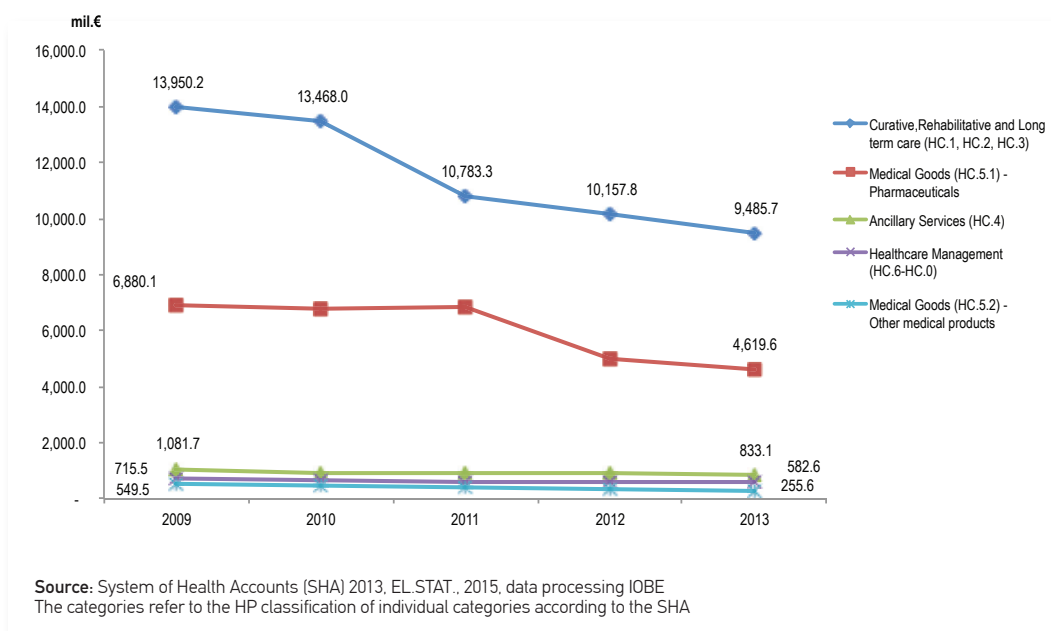
- HC.6 Preventive Care Services & Public Health
- HC.7 Healthcare Management & Social Security Funds
- HC.9 Non-specialized services by type

Note that in the present analysis, the category "Retailers and other providers of medical goods (HC.5)" has been separated to "Pharmaceuticals" (HC.5.1)⁴ and "Other Medical Products" (HC.5.2), so as to have a deeper description of the pharmaceutical spending.

In 2013, expenditure for Curative, Rehabilitative & Long-term care services amounted to € 9.5 bln accounting for the greater proportion of total healthcare spending, followed by total pharmaceutical expenditure with €4.6 bln, ancillary health care services with € 833 million and expenditure for healthcare management (€ 582,6 million.).

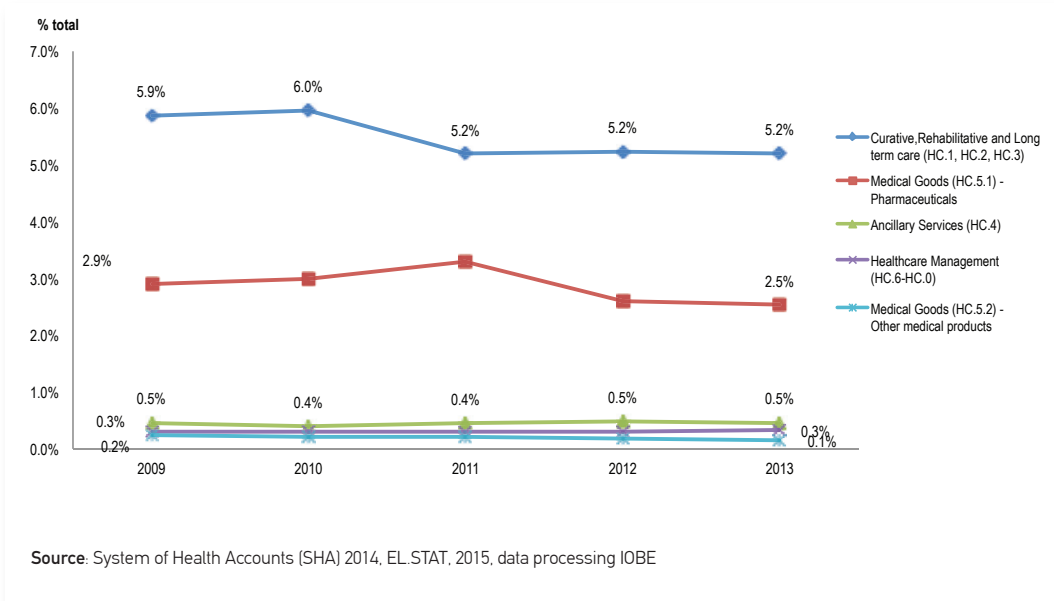
4. This category contains OTC and high-cost products (L.3816/2010).

Figure 15: Total Health Expenditure Components (mil.€)



The following figure depicts health expenditure components as a percentage of GDP (note that during 2009-2013 national income has significantly decreased (-23.2% or €55 bln)). Expenditure for Curative, Rehabilitative and Long Term care services correspond to 5.2% of GDP in 2013, while pharmaceutical expenditure to 2.5% in 2013.

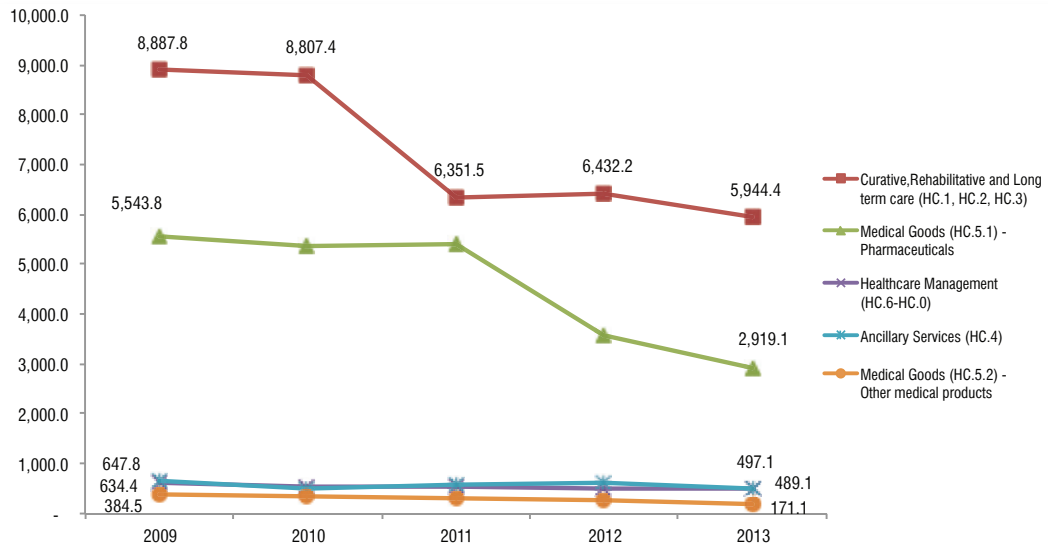
Figure 16: Total Health Expenditure Components (% GDP)



Figures 17 and 18 depict the respective components as part of public health expenditure alone. Public expenditure for Curative, Rehabilitative and Long Term care services and public pharmaceutical care remain the most significant fragments, although they have been reduced from €8.9 bln in 2009 to €5.9 in 2013 and from €5.5 bln to €2.9 bln in 2013 respectively.

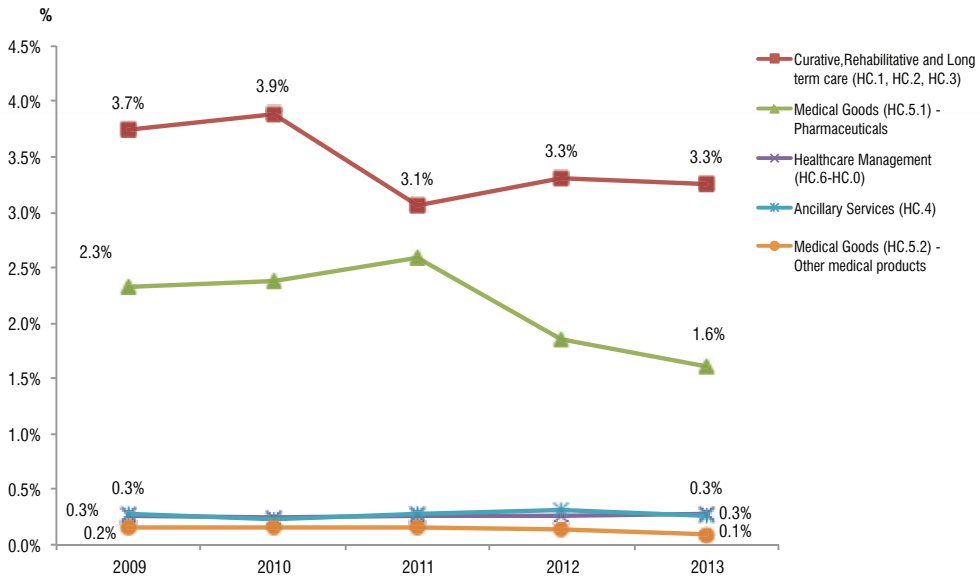
As a percentage of GDP, long-term care faced a small reduction from 3.7% in 2009 to 3.3% in 2013, in contrast to public pharmaceutical expenditure which fell significantly to 1.6% of GDP compared to 2.3% in 2009. Other components of public health expenditure as % of GDP remained stable during the respective period.

Figure 17: Public Health Expenditure Components (bln€)



Source: System of Health Accounts (SHA) 2013, EL.STAT, 2015

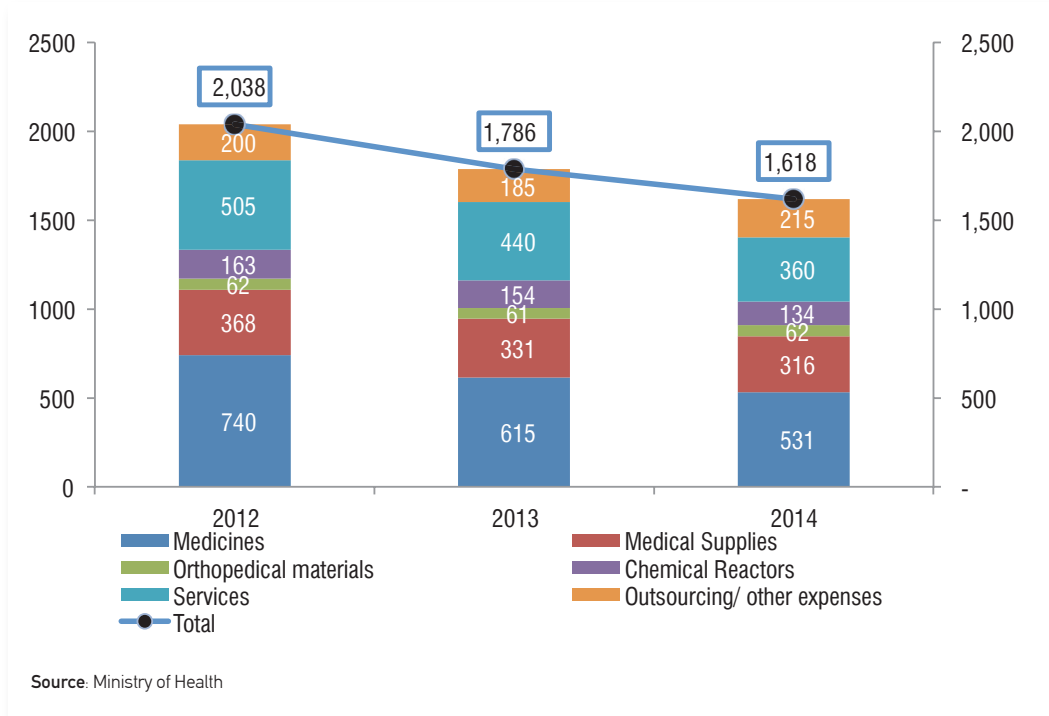
Figure 18: Public Health Expenditure Components (% GDP)



Source: System of Health Accounts (SHA) 2013, EL.STAT, 2015

Reduction in public health expenditure in Greece can also be reflected in the evolution of hospital expenditure. It is noteworthy that during the period 2012-2014, hospital pharmaceutical expenditure was reduced by 20.6%, thus reaching in €1.6 bln from €2.04 bln.

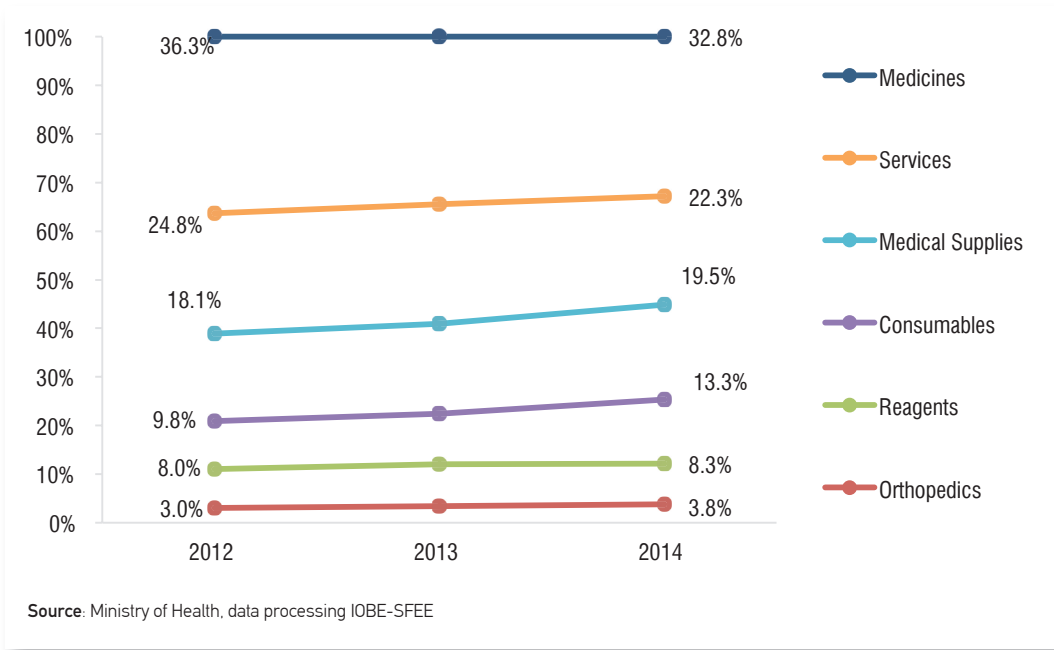
Figure 19: Breakdown of NHS hospitals expenditure, 2012-2014(in mil.€)



This reduction was not allocated equally among the different cost-centers of hospital spending. Specifically, during 2012-2014, the greatest reduction was marked in expenditure for services and medicines reaching 28% followed by the reduction in expenditure for chemical reactors (18%) and expenditure of medical supplies (14%).

According to Figure 20, medicines currently represent 32.8% from 36.3% in 2012 while services represent 22.2% from 24.8% respectively of the hospital expenditure budget. On the contrary, medical supplies and outsourcing exhibited an upward trend to 19.5% and 13.3% respectively.

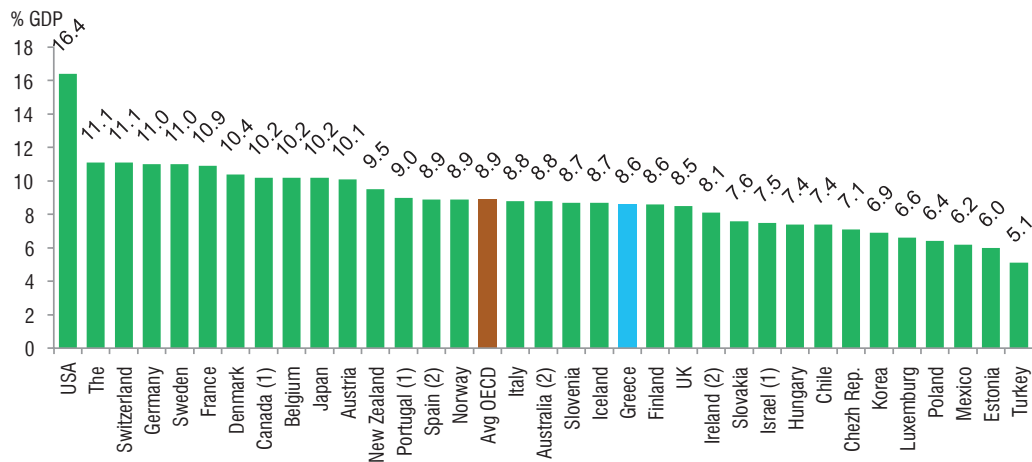
Figure 20: Hospital expenditure evolution, 2012-2014



5.2.1 COMPARISON WITH OTHER COUNTRIES

Health expenditure as a percentage of GDP in Greece in 2013 accounted for 8.6% which is lower than the average of OECD countries (8.9%) but also from countries with economic crisis like Portugal (9%), Spain (8.9%) and Italy (8.8%). It should be noted here that 8.6% corresponds to the new SHA methodology 2011 (see Appendix). According to data from the OECD, appreciated with the old methodology SHA 1.0, health expenditure rate is 9.2%.

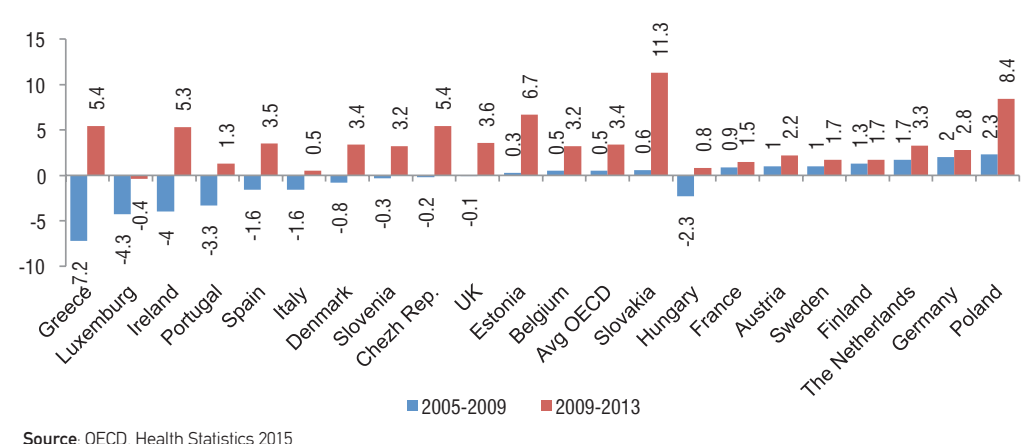
Figure 21: Health Expenditure as a percentage of GDP (OECD countries), 2013



Source: OECD, Health Data 2015, SHA, 2013, (1) Preliminary estimations, (2) Data 2012

Additionally, during the period 2009-2013 per capita health expenditure in Greece decreased by 7.2%, which accounted for the greater reduction among OECD countries, as shown in the figure below.

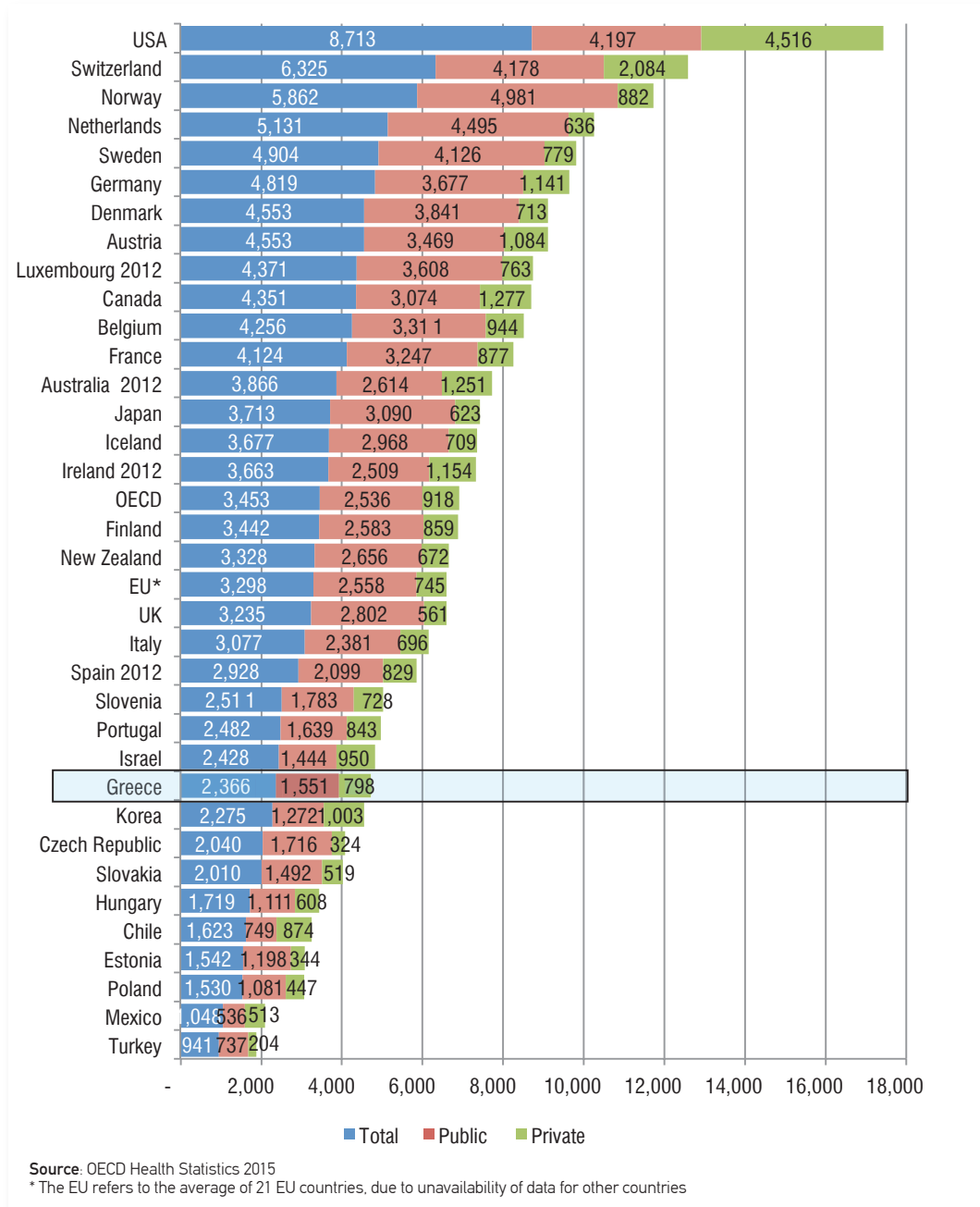
Figure 22: Average per capita health expenditure evolution, OECD



Source: OECD, Health Statistics 2015

Total health expenditure per capita (Figure 23), expressed in \$ PPP⁵, in Greece was 28% lower than the EU average. This was mainly due to the reduction in public health expenditure per capita which was 39.4% lower than EU countries, in contrast to private health expenditure per capita which was the 3rd highest among EU countries and 8th among OECD countries (33.7% Greece 22.6%, 26.6% EU & OECD).

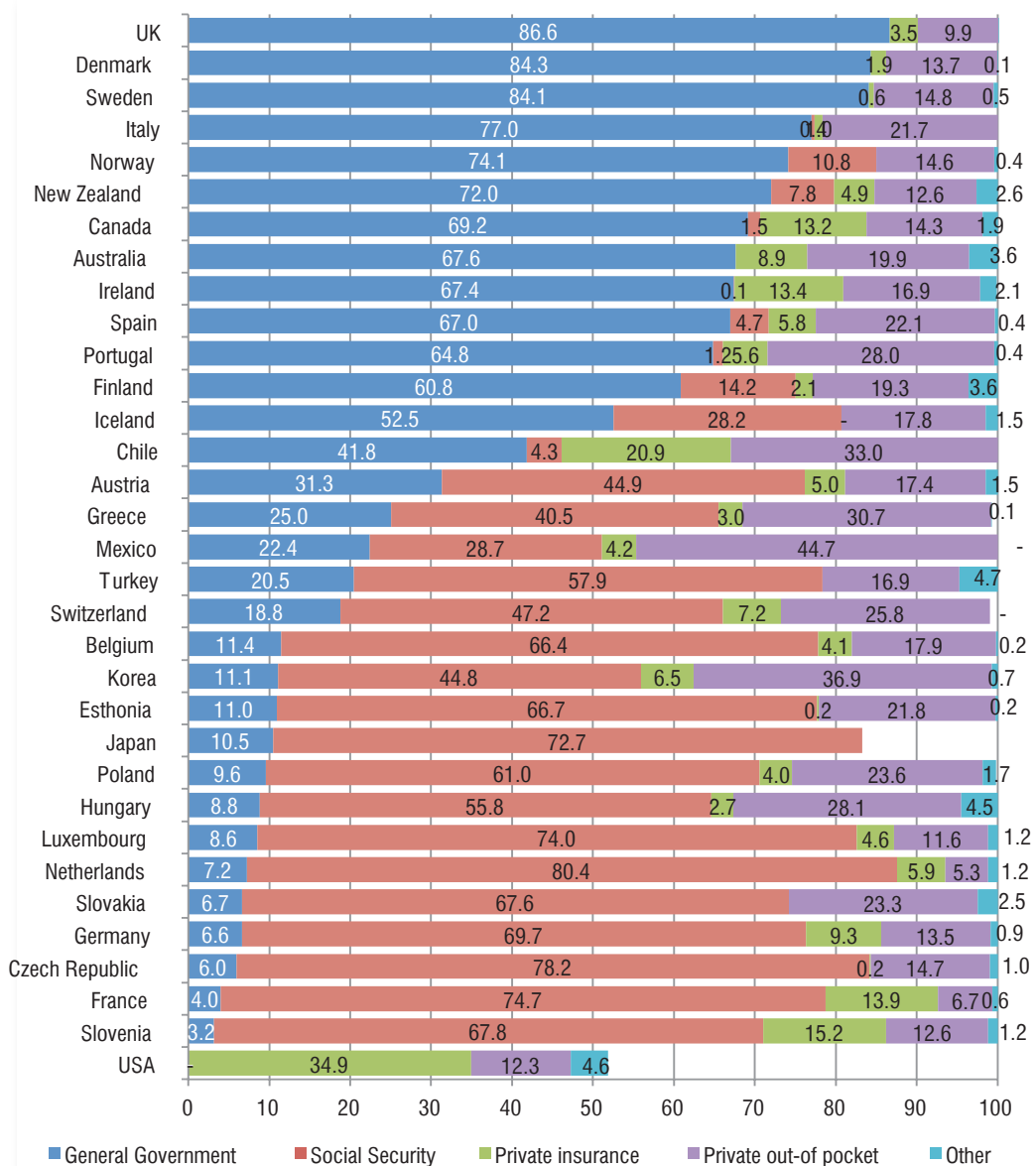
Figure 23: Health expenditure per capita, \$ PPP (Purchasing Power Parity) 2013



5. Purchasing Power Parity

The following figure demonstrates the breakdown of health expenditure by type of financing in each country. In Greece, 25% of expenditure is financed by the general government, while adding social security funds contribution increases the proportion of state funding to approximately 65.5%.

Figure 24: Expenditure on health by type of financing (2013)



Source: OECD Health Statistics 2015

5.3 WELFARE SPENDING AND PUBLIC PHARMACEUTICAL EXPENDITURE

Table 6 represents welfare spending⁶ in Greece comparative to EE-28 average for the period 2008 –2012 (latest available data). Pension and sickness benefits cover the highest share with 72.7% of total spending in Greece and 67.2% respectively in EE-28. It should be noted though that pension benefits in EE-28 represent a significantly smaller proportion of 40.6% of total spending compared to 51.3% in Greece. Differences are noted in other categories as well with disability costs and family allowances exhibiting the greatest differences (7.4% vs. 4.5% (GRE) and 7.8% vs 5.5% respectively) (Figure 25).

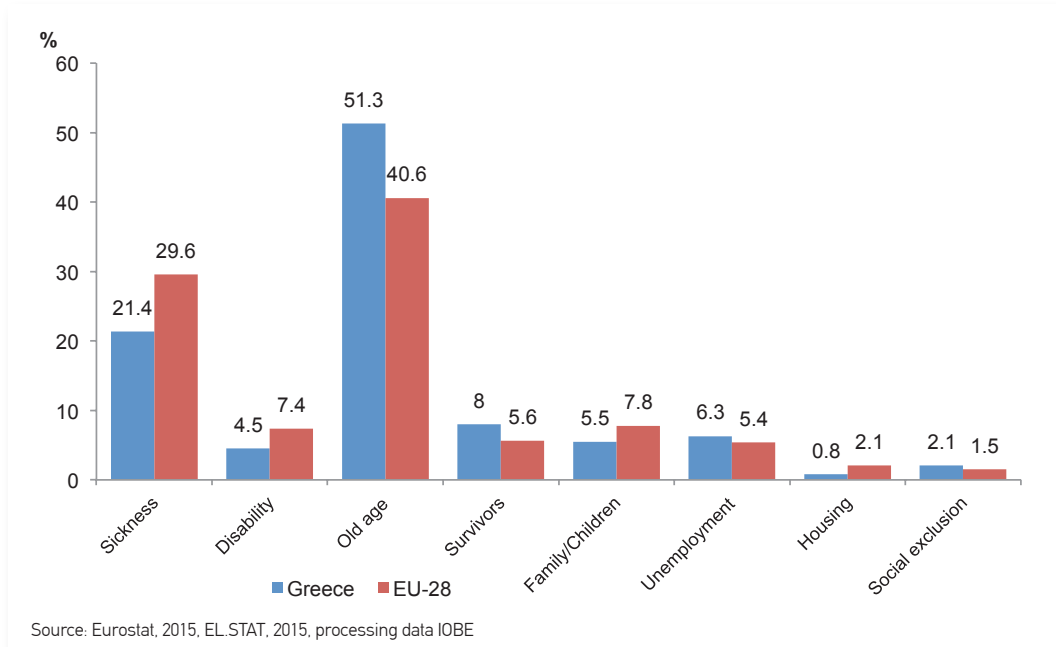
Table 6: Social Protection Expenditure, ESSPROS system - Greece - EU28

GREECE Categories (%of total)	2008	2009	2010	2011	2012	Change %11/12
Sickness/ Health care	29.0	29.1	29.2	25.9	21.4	-20.2%
Disability	4.7	4.7	4.7	4.9	4.5	-11.1%
Old age	42.4	41.4	42.3	44.0	51.3	12.3%
Survivors	8.3	8.2	7.8	8.1	8.0	-4.9%
Family/Children	6.3	6.7	6.4	6.2	5.5	-14.8%
Unemployment	5.1	5.9	6.1	7.4	6.3	-18.0%
Housing	2.0	1.8	1.4	1.3	0.8	-36.4%
Social exclusion	2.2	2.1	2.2	2.3	2.1	-9.1%
Total expenditure (mil.€)	59,204	63,249	62,550	60,165	57,954	-3.7%
EE-28 Categories (%of total)	2008	2009	2010	2011	2012	Change %11/12
Sickness/ Health care	29.6	29.6	29.5	29.6	29.6	3.4%
Disability	7.8	7.6	7.5	7.5	7.4	2.3%
Old age	40.0	39.4	39.7	40.1	40.6	4.8%
Survivors	6.1	5.9	5.8	5.7	5.6	1.7%
Family/Children	8.2	8.1	8.1	8.0	7.8	1.4%
Unemployment	4.9	6.0	5.8	5.5	5.4	1.3%
Housing	2.0	2.0	2.1	2.1	2.1	3.4%
Social exclusion	1.4	1.5	1.5	1.5	1.5	1.7%
Total expenditure (mil.€)	3,212,438	3,345,567	3,474,912	3,550,706	3,673,484	3.5%

Source: Eurostat, 2015, EL.STAT, 2015, processing data IOBE

6. According to the classification system ESSPROS developed by Eurostat, expenditure, which is mainly incurred by social security funds, is broken down into the following categories: Sickness, Disability, Old age, Survivors, Family/Children, Unemployment, Housing and Social exclusion. In Greece, recording of public spending in these categories was done by EL.STAT.

Figure 25: Distribution of social security expenditures in Greece & EU-28



In 2014, welfare spending according to data from the Ministry of Labor (Helios program) amounted to €27.7 bln of which €22.5 bln corresponded to pensions, €3.2 bln for death benefits and €1.7 bln for disability benefits.

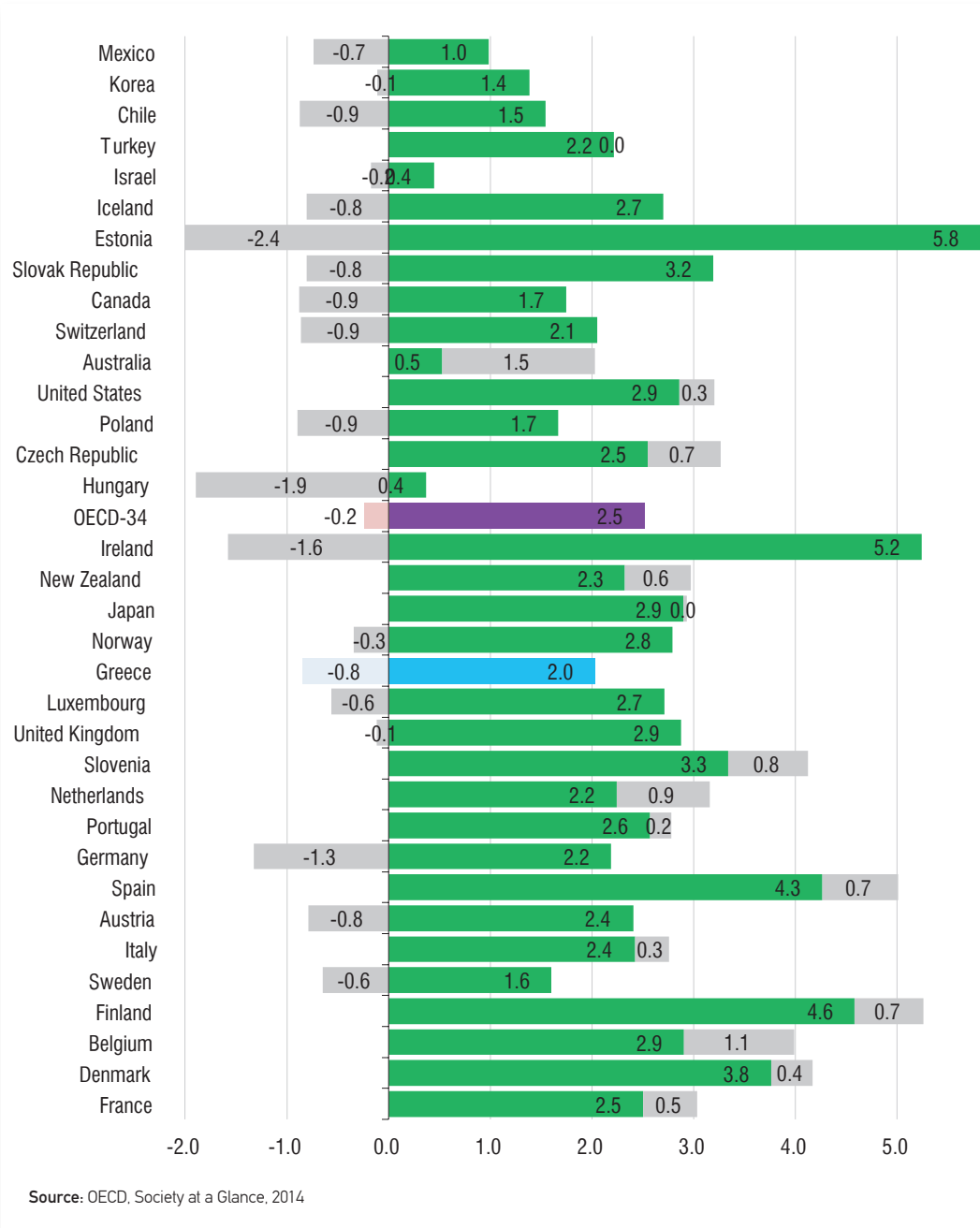
Table 7: Social Protection Expenditure (Helios Program)

	€Billion
Old age	22.573.138.582
Death	3.295.325.605
Disability	1.721.633.199
Uninsured old age (OGA)	133.267.854
Without category	12.904.583
Total	27.736.269.822

Source: Ministry of Labor (Helios program)

During the period 2007-2008 & 2009-2010 an increase in social spending by 2% on average was recorded in both Greece and OECD countries, which was then followed during the periods 2009-2010 & 2012-2013 by a reduction of 0.8% vs. 25% respectively. In the figure below, data for 34 OECD countries, during the same study periods are shown.

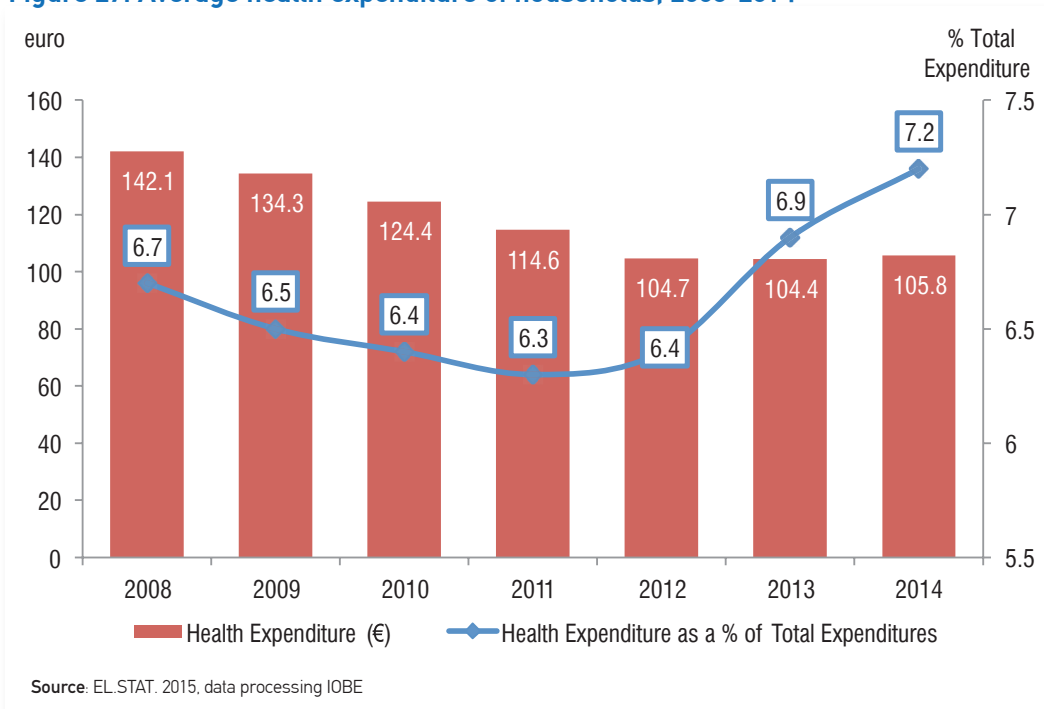
Figure 26: Change in Social protection expenditure (2007-2013)



5.4 HEALTH EXPENDITURE AND PHARMACEUTICAL EXPENDITURE OF HOUSEHOLDS

In absolute terms, average monthly healthcare spending⁷ was reduced by 21% from €134.4 in 2009 to €105.8 in 2014. However, this accounted for 7.2% of total household spending compared to 6.5% in 2009, indicating the reduced purchasing power of households and the increased participation of patients in healthcare spending.

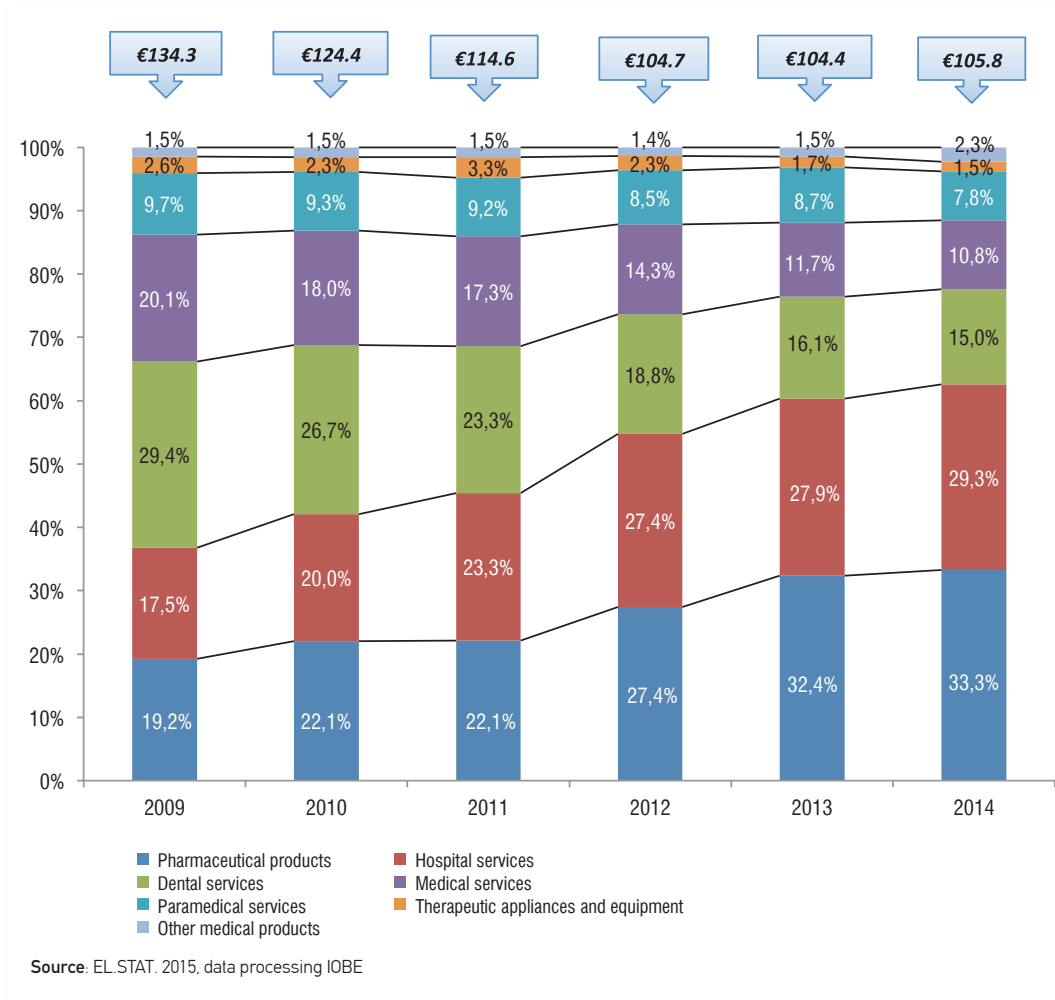
Figure 27: Average health expenditure of households, 2008-2014



As shown in Figure 28 during the economic crisis period there was a shift of household expenditure mainly to pharmaceutical and hospital care. Specifically, from the €105.8 monthly health expenditure per household 33.3% refers to pharmaceuticals, 29.3% to hospital services, 15% to dental services and 10.8% to other medical services.

⁷ Household Budget Survey, which is conducted annually by the ELSTAT, provides information for the composition of total household spending, according to various socioeconomic characteristics of each household.

Figure 28: Breakdown of monthly average household health expenditure, 2008-2014

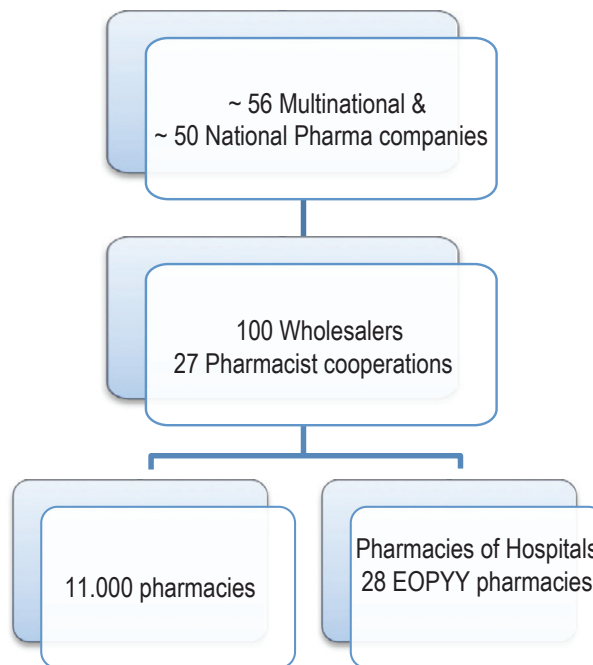


6

THE SUPPLY SIDE: PHARMACEUTICAL INDUSTRY AND ECONOMY

Production and distribution of pharmaceuticals is one of the most dynamic sectors of the Greek economy. In 2014, according to Eurostat, approximately 13.3 thousand people were employed in the manufacturing of medicinal products (employees of the wholesale sector are not included), making the pharmaceutical industry a vital factor for growth in Greece.

The supply chain for pharmaceutical products is comprised of pharmaceutical companies (both manufacturers and importers), wholesalers (both storage and distribution) and pharmacies. All medicinal products are distributed through wholesalers to pharmacies, except products for hospital use only which are provided through sales to hospitals. Direct sales to pharmacies are permitted, as long as pharmacies accept the respective payment policies of the companies. In some occasions, doctors or pharmaceutical companies are allowed to supply patients directly upon approval by the Social Insurance Fund.

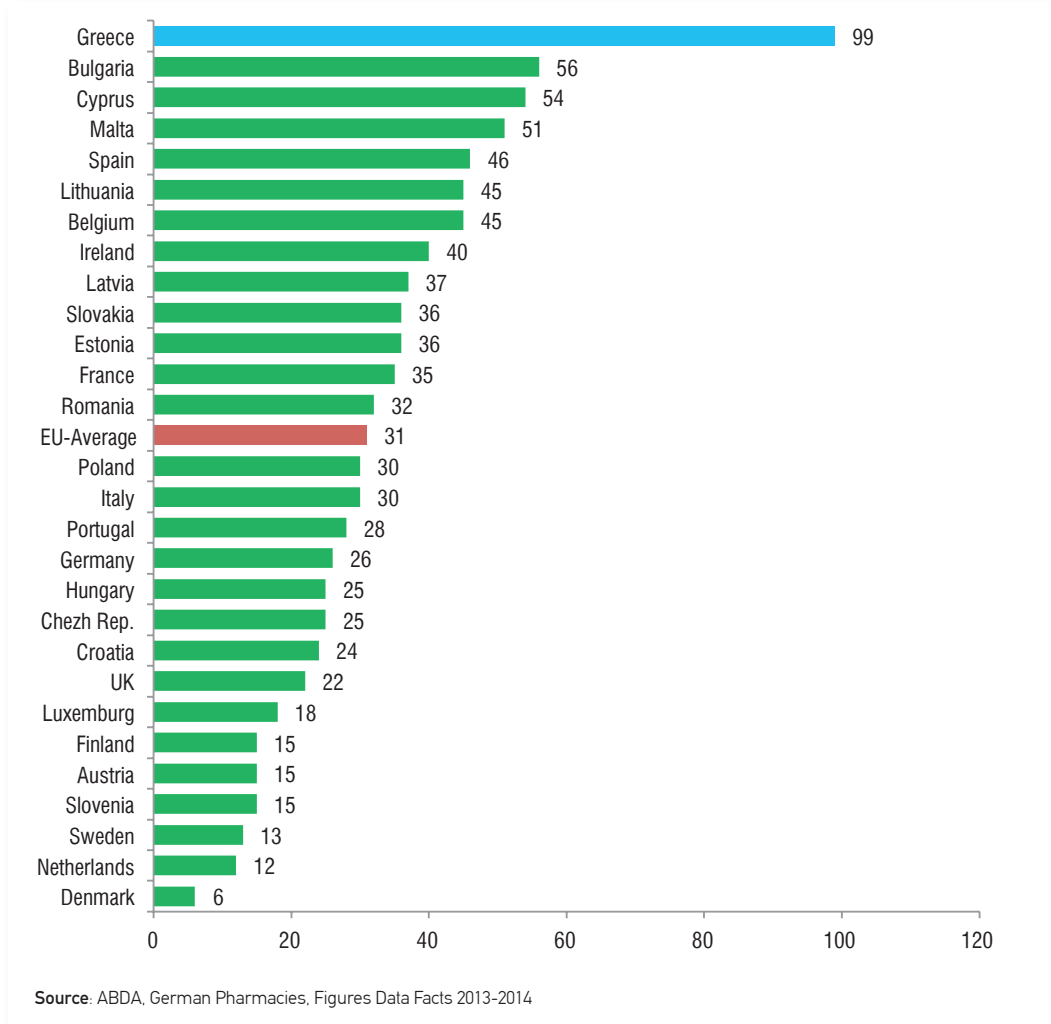


Source: EL.STAT. EOPYY, PanHellenic Association of Pharmaceutical Wholesalers

The wholesale segment of the market is comprised by private wholesalers and pharmacist cooperatives. 100 wholesalers and 27 pharmacist cooperatives operated in the domestic market, based on data from the PanHellenic Association of Pharmaceutical Wholesalers in 2014.

Based on the number of licenses, there are more than 11.000 pharmacies. With a pharmacy density of 99 pharmacies per 100,000 inhabitants, Greece comes first among the EU-28 average of 31 pharmacies per 100,000 inhabitants.

Figure 29: Number of Pharmacies per 100,000 inhabitants, EU 27, 2013



In 2013, (latest data available), the number of wholesalers in Greece reached 100, which is rather high in contrast to other European countries. It is worth noting that every full-line wholesaler in Greece is a separate entity in contrast to European practices, where full-line wholesalers can operate warehouses with many branches (Table 8).

Figure 30: Number of Wholesalers, 2013

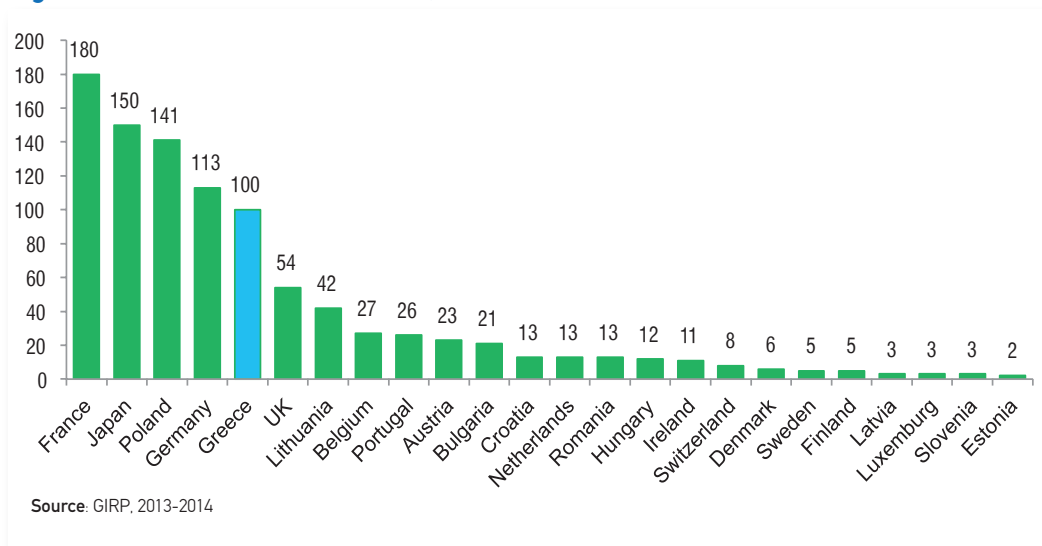


Table 8: Pharmacies and Wholesalers in Greece and Europe, 2013-2014

Country	Pharmacies* 2014	Full-line wholesalers**	Wholesalers** 2013	Ratio Warehouses per Wholesaler
Austria	1,303	7	23	3.3
Belgium	4,998	8	27	3.8
Bulgaria	3,652	3	21	7.0
France	22,655	17	180	10.6
Germany	20,921	13	113	8.7
Denmark	314	2	6	3.0
Switzerland**	1,744	4	8	2.0
Greece	11,000	100	100	1.0
Estonia	469	4	2	0.5
UK	14,186	9	54	6.0
Ireland	1,701	2	11	3.5
Spain	21,458	42	150	3.6
Italy	18,102	52	N/A	
Croatia	1,111	M/Δ	13	
Cyprus	477	M/Δ	N/A	
Latvia**	783	3	3	1.0
Lithuania**	1,383	3	42	14.0
Luxembourg	91	3	3	1.0
Hungary	2,334	7	12	1.7
Netherlands	1,981	5	13	2.6
Poland	11,297	10	141	13.0
Portugal	2,885	46	26	0.6
Romania	7,932	7	13	1.9
Slovakia	1,935	2	N/A	
Slovenia	321	9	3	0.3
Sweden	1,303	3	5	1.7
Czech Rep.	2,450	4	N/A	5.3
Finland	818	2	5	2.5

†Source: *PGEU, 2014 **GIRP, 2013 (Data refer to EU-27 countries, except Cyprus and Malta). N/A: Not Available

EOPYY Pharmacies

The majority of high cost drugs belonging in L.3816 / 2010 list are provided exclusively by EOPYY pharmacies or hospital pharmacies. Based on the ministerial decree published in Government Gazette 64/B' /16-01-2014, the list of high-cost, serious diseases pharmaceutical products that fall under the provisions of L.3816/2010 was split into two distinct lists. The first list relates to pharmaceutical products that are only available for hospital use (1A), while the second list includes those pharmaceuticals, which their use begins in the hospital and can be continued externally. EOPYY initially operated five pharmacies in Attica and one in Thessaloniki. Currently, 28 EOPYY pharmacies are in operation. In areas where EOPYY pharmacies do not exist, the insured can obtain the respective medicines from EOPYY's local health units, after placing an order. Products that are exclusively available for hospital use are sold from EOPYY at hospital price, reduced by 5%, while those in the second list are subject to the prices as regulated by the Ministry of Health.

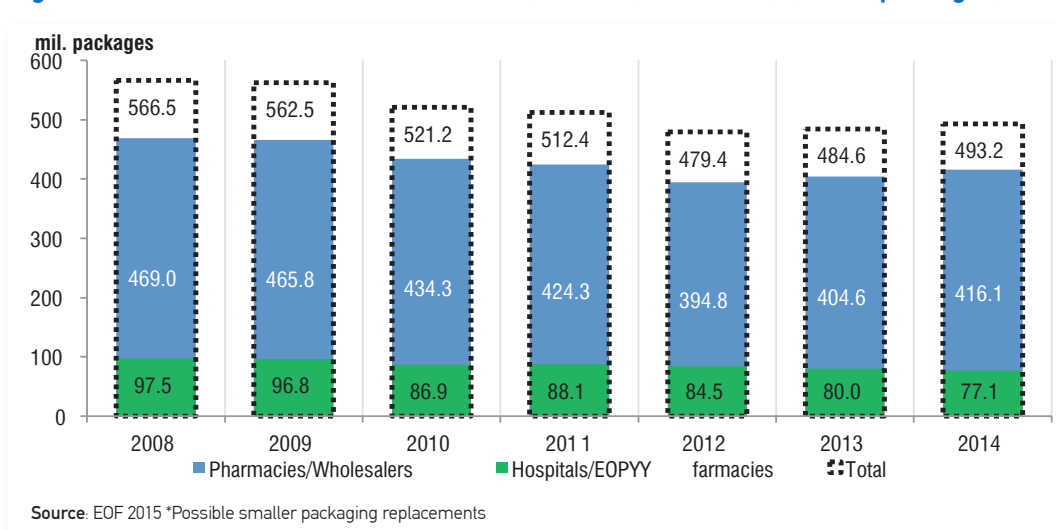
6.1 SALES⁸

Sales of medicinal products to pharmacies/wholesalers amounted to €3.88 bln in 2014, exhibiting a reduction of 2% compared to previous year. On the contrary, sales to hospitals presented an increase of 4.5% respectively. Approximately, 73.5% of total sales were supplied to wholesalers and private pharmacies⁹, while the remaining 26.5% of sales to hospitals & EOPYY pharmacies. It is worth noting that the market has recorded an overall decrease of 44.6% in sales compared to 2009.

Figure 31: Pharmaceutical Sales in values, Greece, 2008-2014 (bln€)



Figure 32: Pharmaceutical Sales in volume, Greece, 2008-2014, (mil. of packages)



8. Total pharmaceutical sales recorded monthly by the National Organization of Medicines (EOF) and include pharmaceutical sales by pharmaceutical companies to hospitals (at hospital prices) and Wholesalers / Pharmacies (at retail prices). Sales also recorded in terms of number of packages.

9. Parallel exports in 2014 were €306.7 mil. and are included here.

Pharmaceutical products can be classified according to their patent protection status. According to IMS, the penetration rate of patent protected medicinal products reaches 11.2%, which is higher than in other European markets (7%) but can be justified by their significantly lower prices compared to other EU countries (0.82 € per unit on average compared to 1.72€).

Respectively, the market share of non-protected pharmaceutical products amounted to 64.2% (off-patent 35.0% & generics 28.7%) showing an upward trend compared to previous years (Figure 33), while a large margin in terms of price is not recorded between them.

Figure 33: Penetration of pharmaceuticals in European countries (in volume) based on patent status

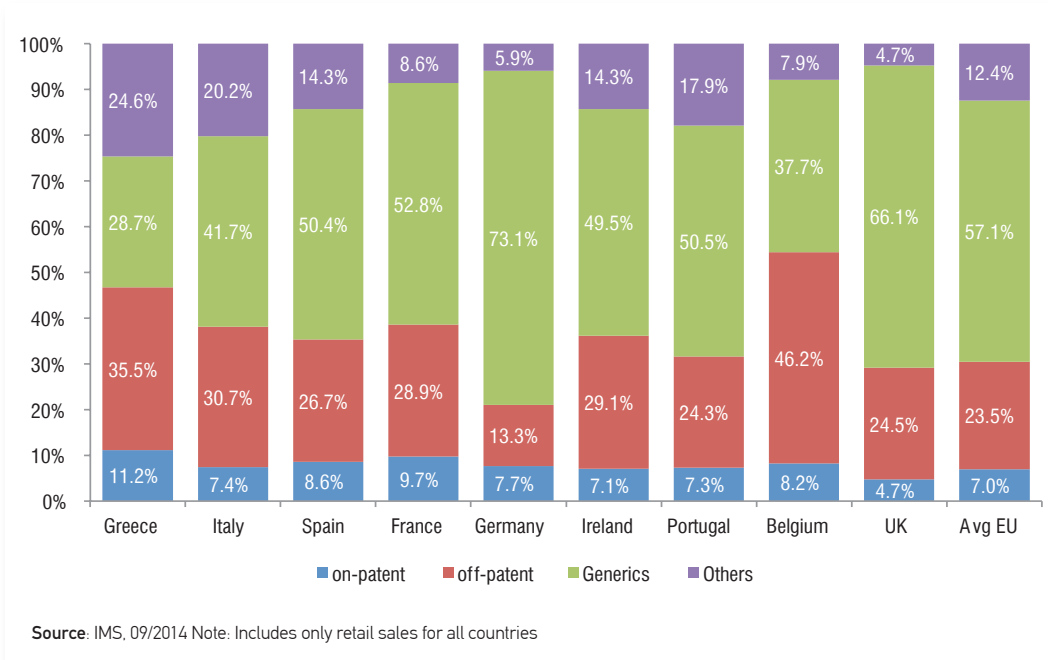
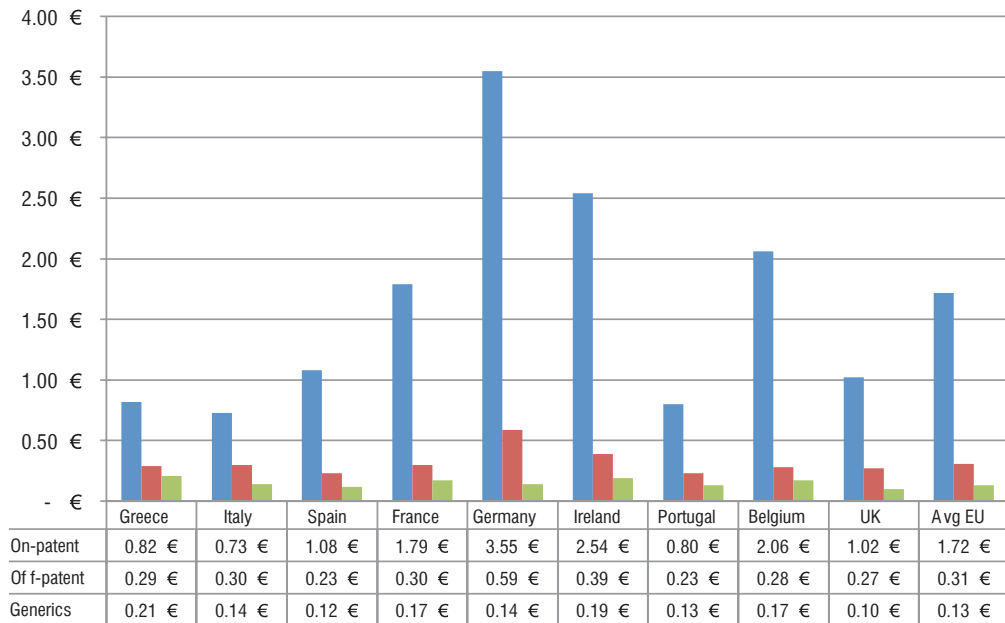


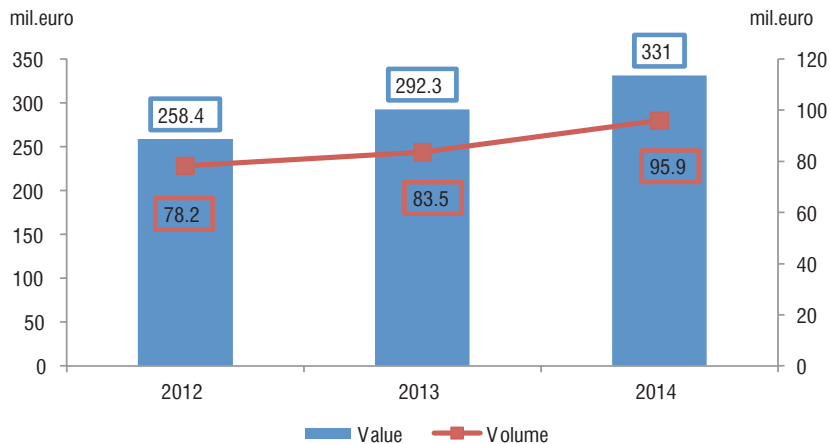
Figure 34: Pricing in European Countries, 2014 (price per unit, €)



Source: IMS, 09/2014 Note: only retail sales are included

Based on latest available data, in 2014 the over-the-counter (OTC) market amounted to €331 mil, showing higher levels than previous years. Analyzing, the number of packages sold in the market for 2014, there is an increase of 14.9% compared to 2013 reaching sales of 95.9 mil packages.

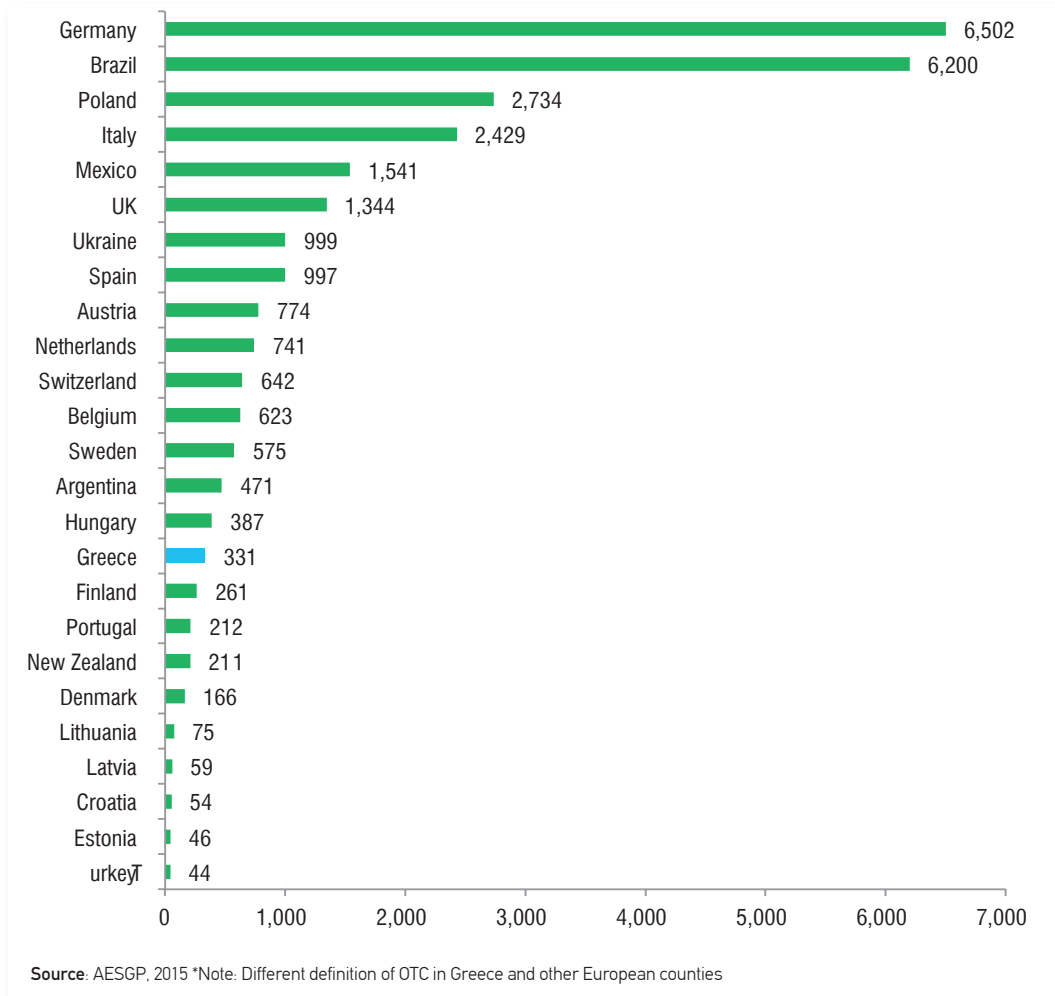
Figure 35: OTC sales, 2012-2014 (in mil. €)



Source: AESGP, 2015, IMS, 2015

Note: Depending on the source of information used, there may be deviations over EOFs' sales data.

Figure 36: OTC total sales in various countries, 2014



OTC share in Greece is among the lowest compared with the rest of Europe. However, it should be noted that the respective market share depends largely on the range of non-prescription medicines included in each country. In 2014, vitamins and minerals (23%) had the greatest share of the market followed by analgesics (20.2%) and cold remedies (19.9%).

Table 9: OTC sales by group in Greece, in mil.€

OTC groups	2012	2013	2014	%13/14	% of total, 2014
Cough and cold	54.5	60.1	66	9.8%	19.9%
Analgesics	56.3	58.9	67	13.8%	20.2%
Digestives	17.3	20.6	24	16.5%	7.3%
Skin treatment	24	27	28.5	5.6%	8.6%
Vitamins and minerals	49.8	62.1	76.2	22.7%	23.0%
Others	56.5	63.6	69.3	9.0%	20.9%
Total	258.4	292.3	331	13.2%	100%

Source: AESGP, 2015, data processing IOBE

6.2 PRODUCTION

According to Prodcum database (Eurostat) in terms of value (ex-factory prices), pharmaceutical production in Greece was estimated at €857 mil in 2014, approximately 2.8% lower than in 2013.

Figure 37: Domestic Production of pharmaceutical products, 2000-2014 (mil. €)

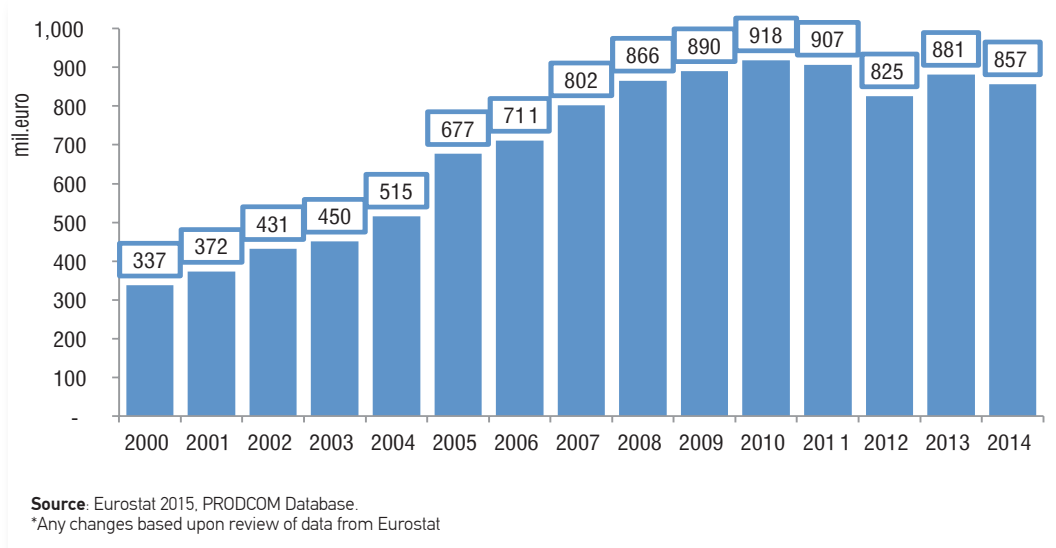
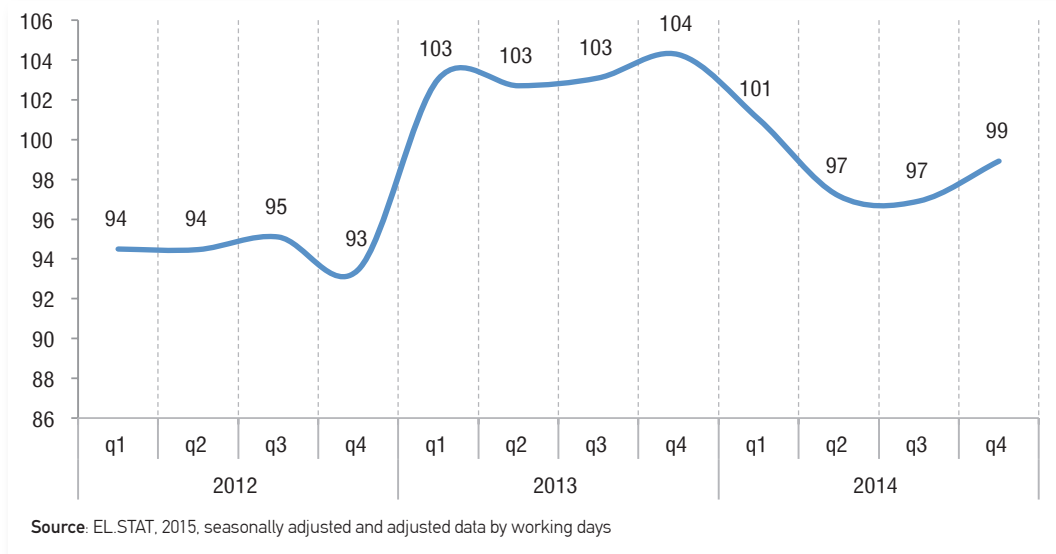


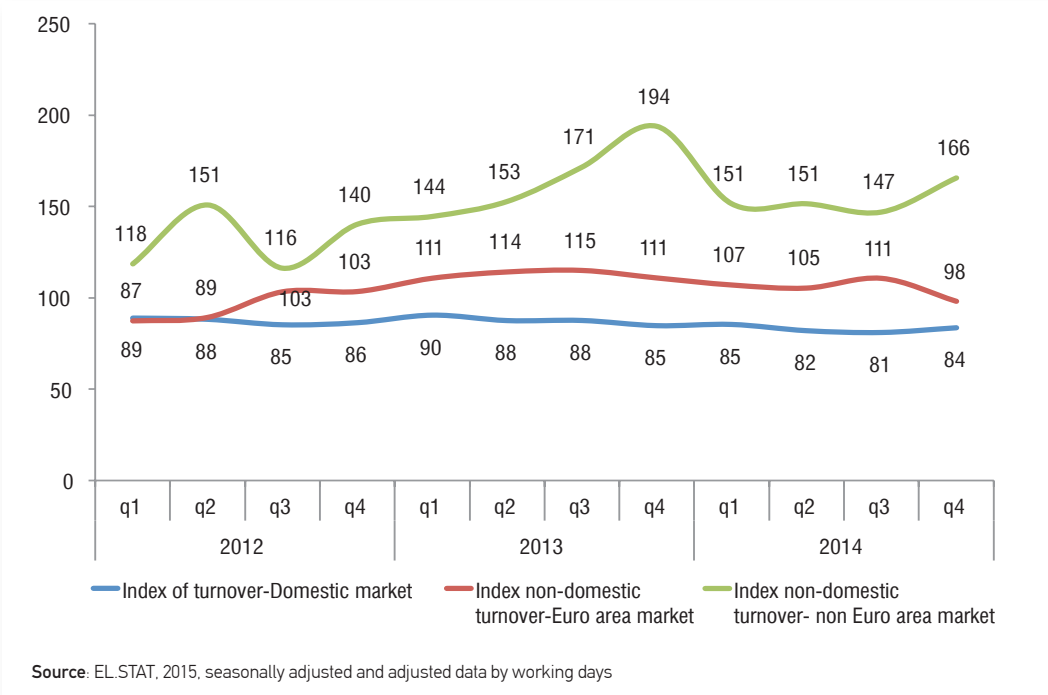
Figure 38 below shows the evolution of production index for the pharmaceutical industry. In particular, the index declined in the first half of 2014, which was then partially compensated by the increase in the second half of the year.

Figure 38: Industrial Production Index for Pharmaceutical goods (2010=100)



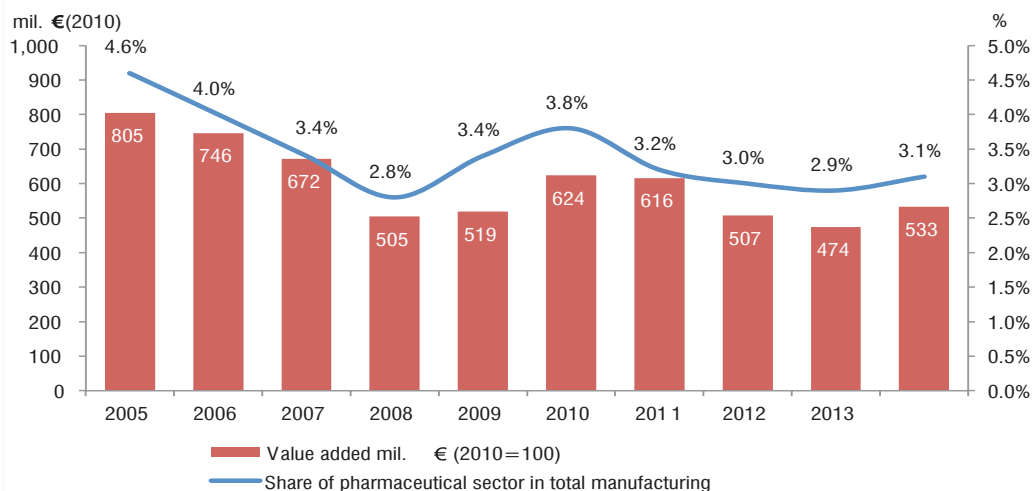
The diagram below shows the evolution of turnover index in the pharmaceutical industry, as a proportion of the turnover in both the domestic market as a whole but also as exports to Eurozone and non-Eurozone countries.

Figure 39: Turnover Index in Pharmaceutical Industry (2010=100)



The importance of the pharmaceutical industry in the years of recession can be represented in the figure below. The added value of the pharmaceutical sector as part of total manufacturing for the country is stabilized near 3% after a recessive period during 2005-2008, despite the economic crisis. When compared with other national manufacturing industries, the pharmaceutical sector is ranked 10th in 2014 (Table 10).

Figure 40: Added Value Pharmaceutical Sector Production



Source: Eurostat, 2015, data processing IOBE

Table 10: Share of added value in Manufacturing 2013

Manufacturing	Share in total Manufacturing 2014
C 10: Manufacture of food products	26.1%
C 19: Manufacture of coke and refined petroleum products	10.4%
C 24: Manufacture of basic metals	10.0%
C: 33: Repair and installation of machinery and equipment	7.4%
C 25: Manufacture of fabricated metal products, except machinery and equipment	6.7%
C 23: Manufacture of other non-metallic mineral products	5.1%
C 11: Manufacture of beverages	4.3%
C 20: Manufacture of chemicals and chemical products	4.2%
C 28: Manufacture of machinery and equipment n.e.c	3.3%
C 21: Manufacture of basic pharmaceutical products and pharmaceutical preparations	3.1%
C 18: Printing and reproduction of recorded media	2.3%
C 14: Manufacture of textiles, wearing apparel	2.3%
C 17: Manufacture of paper and paper products	2.2%
C 27: Manufacture of electrical equipment	1.7%
C 26: Manufacture of computer, electronic and optical products	1.7%
C: 32: Other manufacturing	1.7%
C 12: Manufacture of tobacco products	1.7%
C 13: Manufacture of textiles	1.3%
C 22: Manufacture of rubber and plastic products	1.3%
C 31: Manufacture of furniture	1.3%
C 30: Manufacture of other transport equipment	1.0%
C 29: Manufacture of motor vehicles, trailers and semi-trailers	0.5%
C 15: leather and related products	0.3%

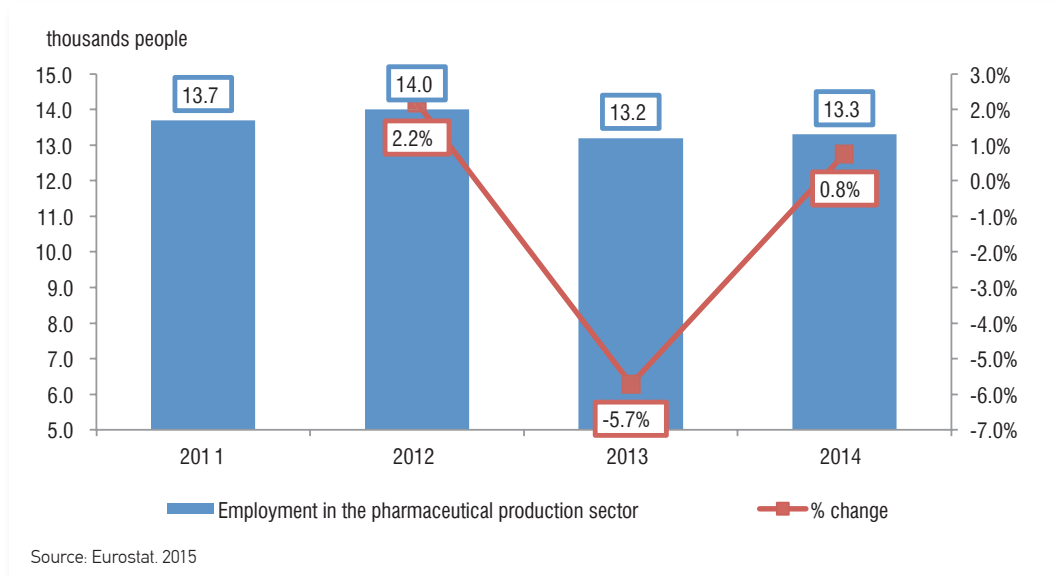
Source: Eurostat (last data 11/11/2015), data processing IOBE, 2015

* C 21: Manufacture of basic pharmaceutical products and pharmaceutical preparations include only the companies active in the production of medicines and pharmaceutical preparations. In C 21 manufacturing companies are not included firms that belong to subsector 46.46 Wholesale of pharmaceutical products.

66.3 EMPLOYMENT

The European pharmaceutical industry is a high-tech sector offering employment to 690.000 people (estimations EFPIA Facts & Figures, 2014). According to Eurostat, in 2014 13.3 thousands people were employed in the manufacturing of pharmaceutical products in Greece, demonstrating a slight increase 0.8% higher compared to the previous year.

Figure 41: Employment in the production of pharmaceuticals



Employment in the pharmaceutical sector represents 0.4% of total employment of the Greek economy, while this share increases to 3.6% with regards to employment in the industrial sector overall. Both shares are higher than the respective average in Europe. It is worth noting that Ireland has the highest share in Europe, representing 13.3% of total industrial employment.

Figure 42: Share of employment in the production of pharmaceuticals in the EU (2014)



According to the International Standard Classification of Education, in the manufacturing sector of medicinal products, the majority of employees 61.3% (8.128 people) have university education (level 5) which indicates the high educational training of the industry.

Table 11: Educational employment structure in pharmaceutical production (2014)

	Sector 21		Total Economy	Total Industry
	Number of persons	Percentage	Percentage	Percentage
1-Primary education or first stage of basic education	563	4.2%	13.6%	15.9%
2-Lower secondary or second stage of basic education	383	2.9%	9.8%	13.9%
3-(Upper) secondary education	3.285	24.8%	33.5%	41.7%
4-Post-secondary non-tertiary education	227	1.7%	9.0%	8.9%
5-First stage of tertiary education	8.128	61.3%	32.5%	19.3%
6-Second stage of tertiary education	666	5.0%	1.0%	0.2%
Total	13.252	100.0%	100.0%	100.0%

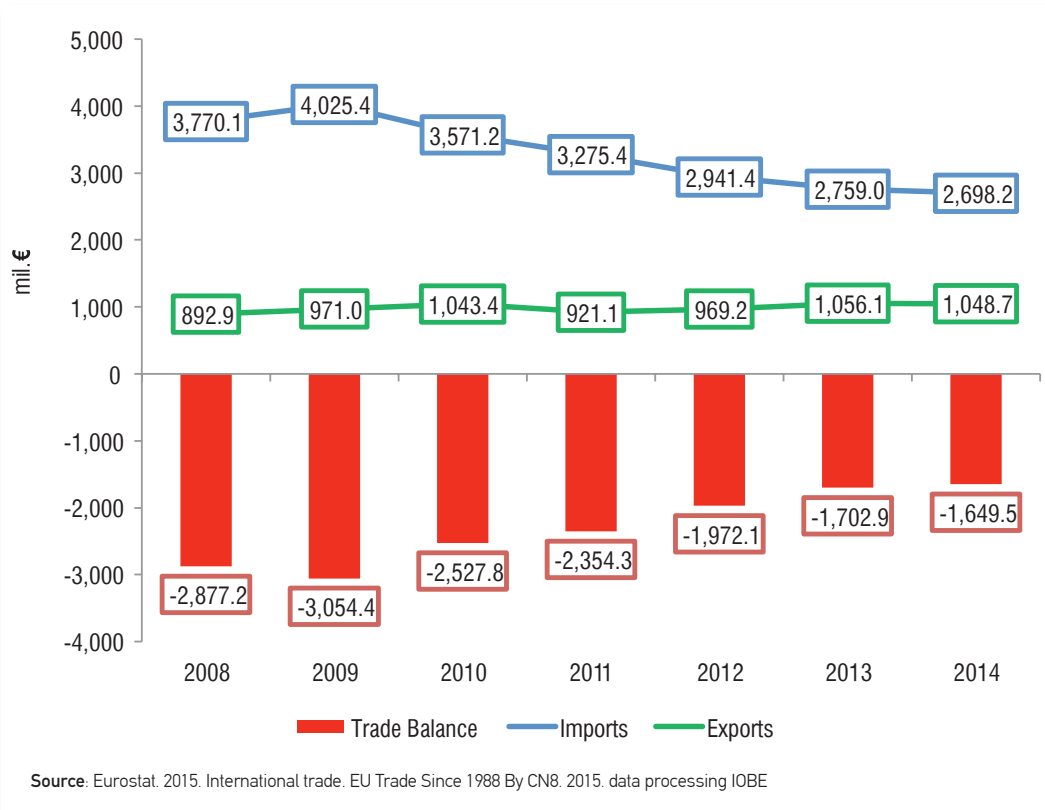
Source: EL.STAT. (ISCED. International Standard Classification of Education – Unesco)

6.4 EXTERNAL TRADE

The pharmaceutical industry is also an important driver for the country's external trade. Imports and exports of medicinal products amounted to €2.7 bln and €1.0 bln respectively in 2014. This is translated to a reduction of 2.2% in imports and 0.7% in exports respectively compared to previous year, thus lowering the pharmaceutical trade deficit by 3.1% at €1.65 bln compared to €1.7 bln in 2013.

It is worth mentioning that based on data from the Panhellenic Exporters Association in 2014 medicinal products are the second export product in value terms after mineral oils in Greece.

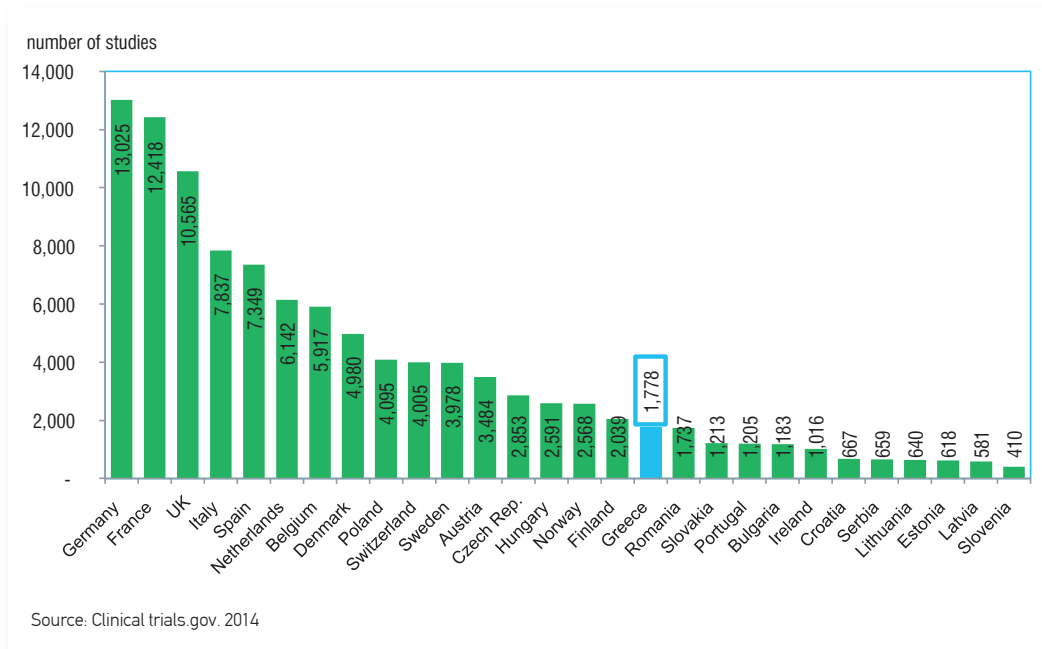
Figure 43: Pharmaceutical Trade Balance (mil.€)



6.4 RESEARCH AND DEVELOPMENT (R&D)

Greece was ranked in the last places among EU countries in the R&D investment list, spending €100-120 mil according to EOF estimations. With respect to the number of clinical studies conducted in 2014, irrespective of phases, it was found that 1.778 clinical studies took place in Greece, which is similar to that in countries such as Romania and far less than countries more research intensive, such as Germany, France and United Kingdom.

Figure 44: Number of Clinical Trials, all phases and stages. 2014



PRICING OF PHARMACEUTICAL PRODUCTS

Prices of medicinal products in Greece are set based on an international price referencing (IPR) system. Specifically, as set by the Law 4213, Chapter 4, art.22, prices for medicinal products are set based on the average of the 3 lowest prices of the EU member-states. The above provisions are specified by ministerial decisions. During 2014 there were significant changes in pricing and profit margins for pharmacists as reflected in Tables 12 & 13.

Ministerial decision GG1907/B/15.7.2014, as described below, sets the provisions under which pricing of pharmaceutical products is currently set out. Any intermediate provisions published within this year are presented in Table 14.

In order for a medicinal product to be priced for the first time, it needs to have been priced in at least three EU member-countries. Only orphan medicinal products may be priced even if prices are available in only two other EU countries.

Maximum wholesaler price (ex-factory) of on-patent products is based on the average of the three lowest prices of the EU member-states which publish reliable data. Respectively, the maximum wholesale price of off-patent products is automatically reduced either to 50% of the last price the product held under patent protection or to the average of the three lowest prices of the EU member-states, respecting the lowest between the two. Generic prices are set to 65% of the price of the respective reference medicinal product.

For the medicinal products for which there is no generic in the market during the last twelve months, based on EOPYY sales, the average of the three lowest prices in the Member States of the European Union is exclusively used. When a generic product becomes available in the market (with sales), its price is reduced by 50%, even if the resulting price is lower than the average of the three lowest prices in the EU Member States. The latter is valid for all medicinal products for which patent protection has expired after 01.01.2012, including the respective generics (market authorization after 01.01.2012 & LOE after 01.01.2012). For those products with loss of exclusivity before 01.01.2012, horizontal price reductions are applied as defined by the respective ministerial decree. Similarly, for generics authorized prior to 01.01.2012.

For medicinal products that are exclusively produced in Greece and/ or have Greek patent rights, price is set based on invoice / tariff which contain production and packaging costs, as well as administration - distribution – dissemination costs and research and development costs.

Prices are revisited regularly downwards each time a price bulletin is issued. Products excluded from repricing are any products belonging in the negative list and OTC list. Exceptionally, for reasons of safeguarding public health and for covering adequately patient needs, blood products are exempted from repricing. Finally, the latter may not be priced lower than the average of the three lowest.

Price definitions

Maximum Wholesale Price: Maximum Wholesale Price of Medicinal Products is the price at which medicinal products are sold to pharmacies. This price includes the gross profit margin of the wholesaler, which is calculated as a percentage on the maximum price of the ex-factory. Gross profit margin (mark-up) a) for all medicinal products reimbursed by social security funds is set as a percentage of 4.9% on the maximum net ex-factory price (up to €200) and 1.5% on the maximum net ex-factory price (>€200) b) for non-prescription medicinal products (OTC) as a percentage of 7.8% on the maximum net ex-factory price and c) for medicinal products that belong to par.2, art.2, L3816/2010 as a percentage of 2% on hospital price. The latter is called as Special Wholesaler Price.

Maximum Retail Price: Maximum Retail Price of Medicinal Products is the price at which medicinal products are sold by pharmacies to consumers, and it is defined by the wholesale price, adding the lawful profit margin of the pharmacy as set out in the respective ministerial decree and the applicable Value Added Tax (VAT 6.5%). In particular, for pharmacies the mark up is determined as follows: a) 35% on the wholesale price for non-prescription medicinal products (OTC) b) 35% on the wholesale price for non-reimbursed prescription products c) for reimbursed products (see Table 6) and for products with price > €3.000 is set a percentage of 2%.

Ex-factory price: The maximum producer's price (ex-factory) is the sale price by the marketing authorization holders (MAHs) to wholesalers and is calculated based on the wholesale price reduced a) for prescription medicinal products which are not reimbursed by the Social Insurance Funds by 4.67%, b) for prescription non-reimbursed medicinal products by 5.12% and c) for non-prescription (OTC) medicinal products by 7.24%.

Maximum Hospital Price: Maximum Hospital Price of Medicinal Products is the price at which medicinal products are sold by the Marketing Authorization Holders to the State, State hospitals, Social Care Units, public law legal entities referred to in par. 1 of Article 37 of Law 3918/2011, pharmacies of private clinics with over 60 beds and EOPYY pharmacies. The maximum hospital price shall be determined on the basis of the ex-factory price reduced by 8,74%.

7.1 PHARMACEUTICAL PRODUCTS PRICE STRUCTURE PROFIT MARGINS OF WHOLESALERS VARY DEPENDING ON

the reimbursement status of each product that is, on whether the product belongs in the positive, negative, OTC list or if they fall under L.3816/2011 provisions and its relative wholesaler price. For medicines belonging in the positive list (and therefore reimbursed by the social security funds) profit margins and the price structure are set as follows:

Table 12: Mark-up in the pharmaceutical supply chain. 2014

	Reimbursed Products up to 200€	Reimbursed Products > 200.01€	OTC	Negative list products
Wholesalers (over ex-factory)	4.9%	1.5%	7.8%	5.4%
Pharmacies	Table 13	Table 13	35%	35%

Source: Ministerial Decision No. 3457.2014 (Gazette of Government B 64)

Για τα φαρμακεία το ποσοστό μικτού κέρδους (mark-up) για όλα τα αποζημιούμενα φάρμακα από τους ΦΚΑ σύμφωνα με το κάτωθι πίνακα.

Table 13: Mark-up for pharmacies

Wholesale price (€)	Percentage mark-up pharmacies
0-50	30.00%
50.01-100	20.00%
100.01-150	16.00%
150.01-200	14.00%
200.01-300	12.00%
300.01-400	10.00%
400.01-500	9.00%
500.01-600	8.00%
600.01-700	7.00%
700.01-800	6.50%
800.01-900	6.00%
900.01-1000	5.50%
1000.01-1250	5.00%
1250.01-1500	4.25%
1500.01-1750	3.75%
1750.01-2000	3.25%
2000.01-2250	3.00%
2250.01-2500	2.75%
2500.01-2750	2.50%
2750.01-3000	2.25%

Source: M.D. (1907/B/15.7.2014)

Mark-up margins mentioned above are the maximum margins allowed in the case of OTC products for both wholesalers and pharmacists, and they are allowed to voluntarily reduce them and offer these products in lower prices as long as it is recorded in the respective invoice.

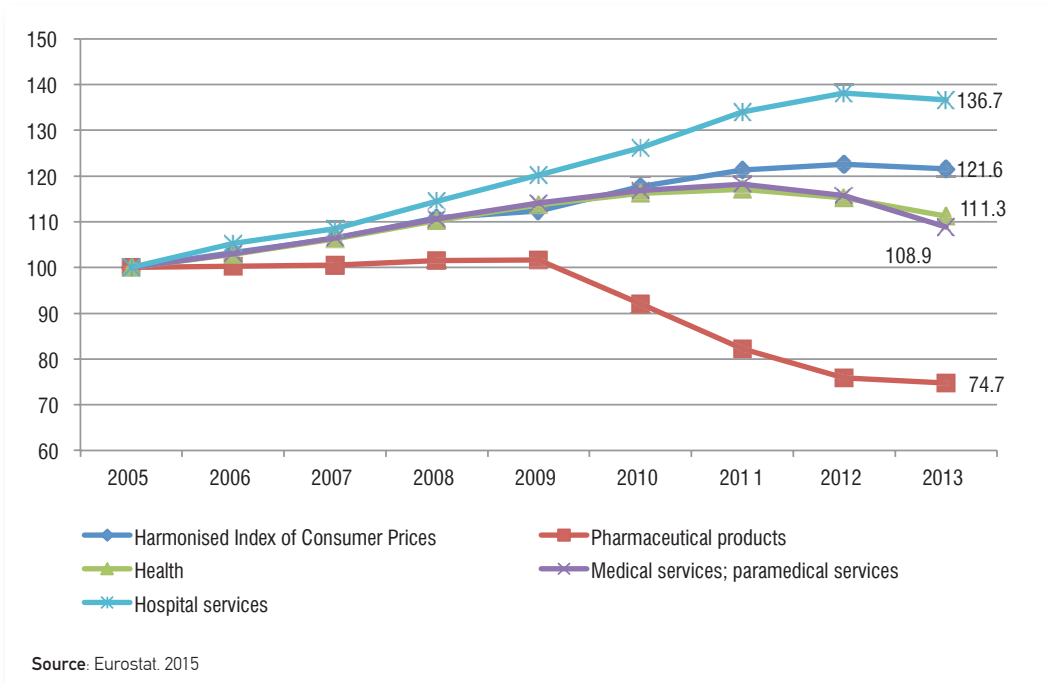
Additionally, these margins are applied to all reimbursed products sold in private pharmacies including products belonging in the L.3816/2010 list. When the latter are directly sold by private pharmacies and the respective cost is not reimbursed by EOPYY or any other SSF, pharmacist margin is set based on the table above and for products with wholesaler price greater than €3.000 this changes to 2%.

According to the price structure of medicinal products, the current rate of 6.0% VAT and the respective profit rates in the supply chain based on wholesale prices (IMS elements 03/2015), the weighted average percentage of the final value attributable to the manufacturer lays at 67.8%, wholesaler at 3.4% and pharmacist to 22.8%

7.2 PHARMACEUTICAL PRICE INDEX

The prices of medicinal products in Greece followed a slightly upward trend until 2009, however, significantly lower than the rate of inflation. Pricing reforms introduced from 2009 onwards led to an overall decline of 26.5% in the pharmaceutical price index until 2013.

Figure 45: Drugs Price Index vs Price Index of other Basic Goods (2005=100)



7.3. REIMBURSEMENT OF PHARMACEUTICALS

Regarding the reimbursement of medicinal products, the most important legislative changes during 2014 are summarized below:

According to Law 4249, Article 127 (GG 73 / 03.24.2014), Social Security Funds reimburse patent protected medicinal products that have received market authorization in Greece after 1.1.2012, if they are reimbursed by Social Security Funds in 2/3 of EU Member - States or in at least 12 EU member- states after an health technology assessment evaluation, provided full compliance with the Community EC Directive 89/105 / EG Directive on transparency. The Minister of Health has the authority to exempt medicinal products which are characterized as essential to the life risk coverage of patients or orphan drugs, only when covered by international clinical protocols. New generics are automatically included in the list if the reference medicinal products (off patent) are also included.

The positive list is prepared by EOF and after approval from the Minister of Health it is published in Government Gazette. Following either price revision or after price setting of new medicinal products, the positive list and the corresponding reference values must be reviewed within 30 days (GG64 / 01.16.2014).

For the setting up, the revision and the completion of the reimbursement list, the system of Anatomical Therapeutic Chemical Classification (Anatomic Therapeutic Chemical classification - ATC) from World Health Organization (WHO) is used and a reference pricing system by therapeutic category is applied. The reference price is calculated for each available strength and/or pack size in each cluster.

As defined in the ministerial decision published in GG1144 / 05.06.2014, the reference price is calculated as the weighted average of the lowest cost of daily treatment generics that account for 20% of market sales during the last six months prior to the calculation of prices. Sales are based on EOPYY expenditure.

In cases where a patient chooses a medicinal product with retail price equal to the reimbursement price, then he pays the statutory co-payment (0%, 10%, or 25%). In cases, where the patient decides to choose a product where retail price is greater than the reimbursement price, then he must pay the set co-payment and additionally the full difference between these prices. Finally, when the retail price is lower than the reimbursement price, up to 50% of the difference between them is deducted from the set co-pay. Based on the ministerial decision published in GG1276/20.05.2014, the maximum amount a patient can pay on top of the set co-pay cannot exceed € 50 per pack. Finally, all pharmaceutical products belonging in L.3816 / 2010 list are fully reimbursed by SSFs and are available to patients without co-payment.

It should be noted that based on a later ministerial decision (GG2243/18.08.2014), in cases where a medicinal product with **no generic presence** is chosen, and its retail price is greater than the reimbursement price, patient must pay 50% of the difference between the prices on top of the set co-pay and the remaining 50% is paid by pharmaceutical companies in the form of a rebate, starting from 15.09.2014 onwards.

Table 14: Legislative changes re pricing, reimbursement & rebates, 2014

Ημερομηνία	Gazette / Ministerial Decision	Law
PRICING		
16.1.2014	MD 3457 - GG 64/B	Pricing Provisions
21.01.2014	MD 3594 - GG 18	Pricing Provisions
07.02.2014	MD 12449 - GG 256/B	Pricing Provisions – amendment of GG64B
06.05.2014	MD 38733 & MD 38714 - GG 1144/B	Pricing & supply provisions for OTC
20.05.2014	MD 43066 - GG 1277/B	Pricing Provisions & L.3816/2010 list
04.06.2014	MD 45001 - GG 1435/B	Supply & administration provisions for medicinal products
10.06.2014	MD 49515 - GG 1530/B	Pricing Provisions
02.07.2014	MD 58430 - GG 1805/B	Pricing Provisions
15.07.2014	MD 61771 – GG 1907/B	Pricing Provisions
24.07.2014	MD 65470 - GG 2013/B	Pricing Provisions
31.12.2014	MD 112654 - GG 3677	Pricing Provisions
REIMBURSEMENT		
16.1.2014	MD 3457 - GG 64/B	Pricing Provisions, article 14
13.02.2014	MD 14228 - GG 329/B	Revision of reimbursement list
07.03.2014	MD 21261 - GG 572/B	Approval of reimbursement list
24.03.2014	Law 4249 - GG 73/A	Reorganization of Greek Police (article 127)
26.03.2014	MD 22405 - GG 740/B	Approval of reimbursement positive list
06.05.2014	MD 38733 & MD 38714 - GG 1144/B	Pricing Provisions – Amendment of article 14, GG 64B
10.05.2014	Law 4262 - GG 114/A	Authorisation for economic activity and other provisions (article 54)
14.05.2014	MD 38907 - GG 1222/B	Updated OTC list
14.05.2014	Law 4263 - GG 117/A	Midterm Fiscal Term Strategy 2015-2018
20.05.2014	MD 43066 - GG 1277/B	Approval of Reimbursement list
20.05.2014	MD 43063 & MD 43063 - GG 1277/B	Cap to co-payment-50€/package
06.06.2014	MD 49516 - GG 1511/B	Provisions for the prescription and reimbursement of oncological medicinal products
11.07.2014	MD 60490 - GG 1894/B	Approval of reimbursement list
21.07.2014	MD 62836 - GG 1981/B	Updated OTC list
30.07.2014	MD 66788 - GG 2083/B	OTC List
29.08.2014	MD 74288 - GG 2336	Reimbursement list
16.12.2014	MD 108477 - GG 3376/B	Reimbursement list
REBATES		
16.1.2014	MD 3457GG 64/B	Pricing Provisions
17.02.2014	Law 4238/2014 - GG 38/A	Article 52 Offsetting state debts with rebates & clawback
10.05.2014	Law 4262 - GG 114/A	Supplementation of Article 54 - calculation of clawback
23.05.2014	MD 41767 / GG1322	Offsetting of second half 2013 EOPYY, hospitals and MAHs
18.08.2014	MD 70519 & MD 70520 - GG 2243/B	Rebate & Claw back
18.08.2014	MD 70522 - GG 2247/B	Rebate
31.12.2014	MD 6931 - GG 3676/B	Modification of Ministerial Decision 50-50

STATE'S DEBT TOWARDS PHARMACEUTICAL FIRMS

The Hellenic Association of Pharmaceutical Companies (SFEE) collects and records data related to State's debts of its member companies (on a voluntary basis). Below an overview of total receipts, sales invoices and debts until 31.12.2014 only for the pharmaceutical industry (end date of data collection 31.12.14) are presented. The data collected refer to invoices in the period described above.

Data for sales, receipts and outstanding debts re NHS hospitals, EOPYY, Military hospitals, judicial hospitals, private entities and IFET are requested. However, comparable data from all companies refer to outstanding debts from NHS, EOPYY and military hospitals, which also constitute the largest part of health expenditure.

Specifically, findings show that:

- The total amount of **sales** of SfEE member-companies to the State during the period 01.01.2013 to 31.12.2014 amounted to **€1.943 mil.**, while respective receipts amounted to **€1.314 mil.** (Note: The aforementioned amounts are part of the total, as they involve only companies – members that they have sent detailed data of sales-receipts).
- The total amount of outstanding debts from the State re invoices until 31.12.2014 amounted to €789.9 mil. It should be noted that any debts remaining unsettled before 31.12.2012 are also included here (estimated to €31.9 mil). If broken down to each stakeholder, €496.1 mil account for EOPYY, €276 mil for NHS Hospitals and €17.7 mil for Military Hospitals. (These amounts include also companies which sent aggregated data).
- The settlement of state debts for 2013 is almost completed (94.86% paid back).
- Despite the downward trend shown in Figures 46 & 47, only 40.1% of state debts for 2014 have been paid back. In particular, 56% of NHS hospitals debts and 30.2% of EOPYY debts have been settled for 2014.

It becomes evident that pharmaceutical companies are significantly behind in settling state debts both standalone and comparative to other providers such as pharmacies, private clinics, diagnostic centres, etc. A stable repayment policy must be established directly so as to avoid inability of pharmaceutical companies to support both the market and their businesses.

Figure 46: Total State debts evolution towards SfEE member companies' until 31.12.2014

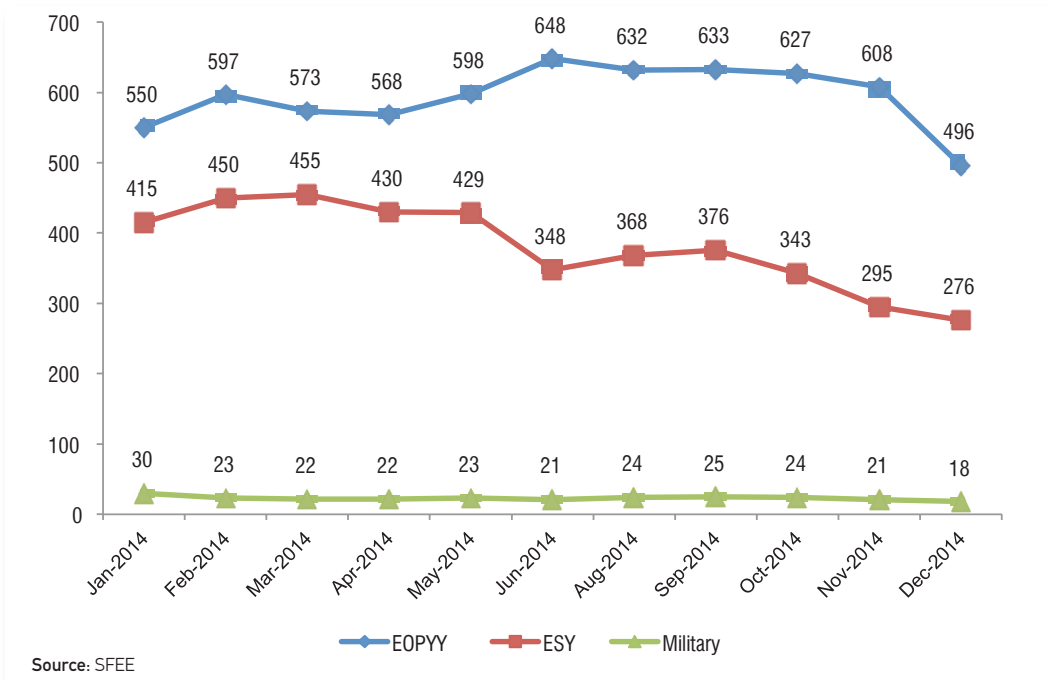
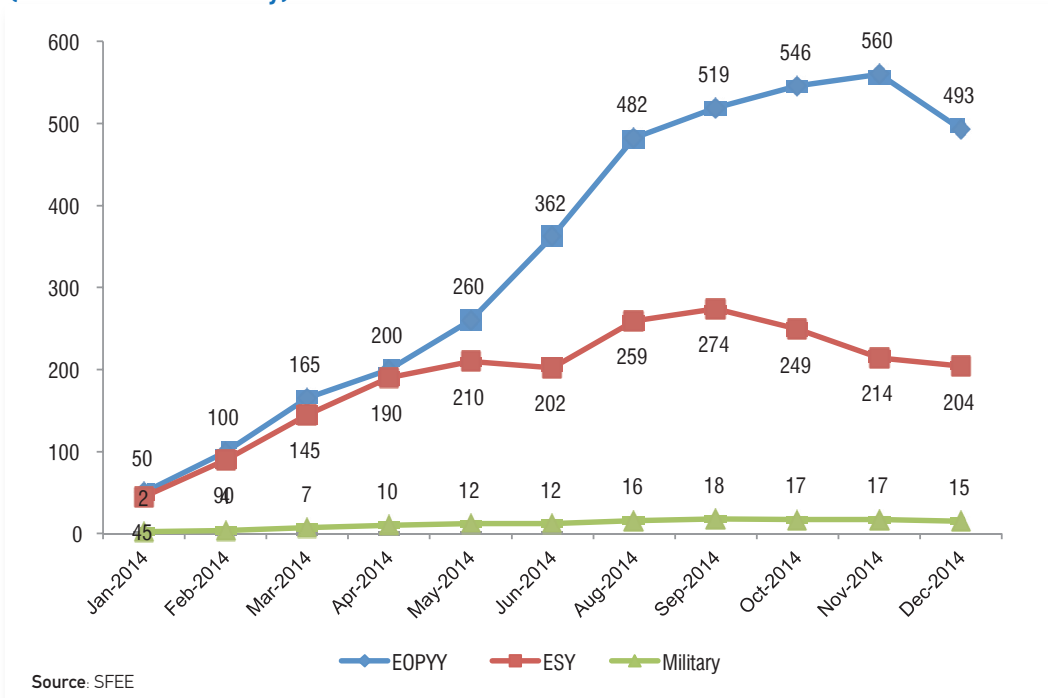


Figure 47: State debts evolution towards SfEE member companies' until 31.12.2014 (Invoices for 2014 only)



9 APPENDIX

Based on article 6 of the European Regulation (EU) 1338/2008 of the European parliament re matters of public health and the respective under voting Implementation Regulation and in cooperation from OECD & WHO the new compilation of SHA data was created. As such, ELSTAT was obliged to communicate SHA data to Eurostat and to International Organizations (OECD and World Health Organization) according to the new SHA 2011 and a revision was done from 2009-2013.

Transition table from SHA 1.0 to SHA 2011 codes

System of Health Accounts SHA 1.0	Funding Sectors (HF)	System of Health Accounts SHA 2011
HF.1.1	General Government (excl. Social Security Funds)	HF.1.1
HF.1.2	Social Security Funds (SSFs)	HF.1.2
HF.2.2	Private Voluntary Insurance Schemes	HF.2.1
HF.2.3	Private Households Out-of pocket Expenditures	HF.3.1
HF.2.4	Non Profit Institutions Financing Schemes	HF.2.2
HF.2.5	Corporation Financing Schemes	HF.2.3
HF.3	Rest of the World	HF.4
HF.0	n.e.c	HF.0
System of Health Accounts SHA 1.0	Health care providers (HP)	System of Health Accounts SHA 2011
HP.1	Hospitals (public and private)	HP.1
HP.2	Residential. Long-term care facilities	HP.2
HP.3.1-3.4. HP.3.6	Providers of ambulatory health care	HP.3
HP.3.5. HP.3.9	Providers of ancillary services	HP.4
HP.4	Retailers and other providers of medical goods	HP.5
HP.5	Providers of preventive care	HP.6
HP.6	Providers of health care system administration and financing	HP.7
HP.7	Rest of Economy	HP.8
HP.9	Rest of the World	HP.9
HP.0	n.e.c	HP.0

Codification at the category of health care activities (HC-health care) remains unchanged between SHA 2011 & SHA 1.0.

